

S/N Unknown

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	David J. Grainger et al.	Examiner:	Unknown
Serial No.:	Unknown	Group Art Unit:	Unknown
Filed:	Herewith	Docket:	295.009US4
Title:	PREVENTION AND TREATMENT OF CARDIOVASCULAR PATHOLOGIES		

INFORMATION DISCLOSURE STATEMENT

BOX PATENT APPLICATION

Commissioner for Patents
Washington, D.C. 20231

Sir:

In compliance with 37 C.F.R. § 1.56, and in accordance with 37 C.F.R. §§ 1.97 *et. seq.*, the enclosed materials are brought to the attention of the Examiner for review in connection with the above-identified patent application. Applicant respectfully requests that this Information Disclosure Statement be entered and the documents listed on the attached Forms 1449 be considered by the Examiner and made of record. Pursuant to MPEP 609, Applicant requests that a copy of Forms 1449, initialed by the Examiner to indicate that all listed documents have been considered, be returned with the next official communication.

In accordance with 37 C.F.R. § 1.98(d), copies of the listed documents are not provided as these documents were previously cited by or submitted to the U.S. Patent Office in connection with Applicant's prior U.S. applications, which are relied upon for an earlier filing date under 35 U.S.C. § 120. This application is a continuation application of U.S. application Serial No. 09/754,775, filed January 04, 2001, which is a continuation application of U.S. application Serial No. 08/973,570, filed December 05, 1997, which is a national stage filing of PCT/US96/10211, filed June 7, 1996, which is a continuation-in-part of U.S. application Serial No. 08/478,936, filed June 7, 1995; U.S. application Serial No. 08/476,735, filed June 7, 1995; U.S. application Serial No. 08/477,393, filed June 7, 1995; and U.S. application Serial No. 08/486,334, filed June 7, 1995, which is a continuation-in-part of U.S. application Serial No. 08/242,161, filed May 12, 1994, which is a continuation-in-part of U.S. application Serial No. 08/061,714, filed May 13, 1993.

INFORMATION DISCLOSURE STATEMENT

Serial Number: Unknown

Filing Date: Herewith

Title: PREVENTION AND TREATMENT OF CARDIOVASCULAR PATHOLOGIES

Page 2

Dkt: 295.009US4

The Examiner is invited to contact the Applicant's Representative at the below-listed telephone number if there are any questions regarding this communication.

Respectfully submitted,

DAVID J. GRAINGER ET AL.

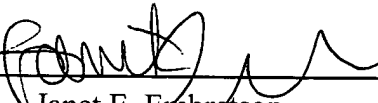
By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 373-6959

Date

December 5, 2003

By


Janet E. Embretson
Reg. No. 39,665

"Express Mail" mailing label number: EV332567201US

Date of Deposit: December 5, 2003

This paper or fee is being deposited on the date indicated above with the United States Postal Service pursuant to 37 CFR 1.10, and is addressed to The Commissioner for Patents, Mail Stop Patent Application, P.O. Box 1450, Alexandria, VA 22313-1450.

Form 1449*	Atty. Docket No.: 295.009US4	Serial No. Unknown
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Applicant: David J. Grainger et al.	
	Filing Date: Herewith	Group: Unknown

U.S. PATENT DOCUMENTS

**Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
_____	2,914,563	11/24/1959	Allen et al.	260	570	08/06/57
_____	3,010,965	11/28/1961	Elpern	260	293	02/05/57
_____	3,168,565	02/02/1965	Palopoli et al.	260	570.7	11/20/59
_____	3,288,806	11/29/1966	DeWald et al.	260	326.5	03/23/64
_____	3,634,517	01/11/1972	Palopoli et al.	260	590	08/19/68
_____	3,940,422	02/24/1976	Harita et al.	260	340	01/17/74
_____	4,070,484	01/24/1978	Harita et al.	424	319	12/21/76
_____	4,093,709	06/06/1978	Sok Choi et al.	424	19	01/28/75
_____	4,133,814	01/09/1979	Jones et al.	260	326	09/17/76
_____	4,230,862	10/28/1980	Suarez et al.	546	237	08/03/78
_____	4,235,988	11/25/1980	Fildes et al.	528	79	05/31/79
_____	4,239,778	12/16/1980	Venton et al.	424	305	09/12/78
_____	4,307,111	12/22/1981	Crawley	424	278	04/29/80
_____	4,323,707	04/06/1982	Suarez et al.	564	324	05/12/80
_____	4,380,635	04/19/1983	Peters	546	324	05/12/80
_____	4,418,068	11/29/1983	Jones	424	267	12/16/81
_____	4,442,119	04/10/1984	Magarian et al.	424	274	07/26/82
_____	4,512,762	04/23/1985	Spears	604	21	11/23/82
_____	4,536,516	08/20/1985	Harper	514	574	04/17/84
_____	4,675,189	06/23/1987	Kent et al.	424	490	02/08/85
_____	4,696,949	08/29/1987	Toivola et al.	514	648	05/25/83
_____	4,824,436	04/25/1989	Wolinsky	604	53	04/21/87
_____	4,826,672	05/02/1989	Milius et al.	424	1	06/07/85
_____	4,835,002	05/30/1989	Wolf et al.	426	590	07/10/87
_____	4,839,155	06/13/1989	Mccague	424	1	09/09/87
_____	4,859,585	08/22/1989	Sonnenschein et al.	435	29	04/17/86
_____	4,879,315	11/07/1989	Magarian et al.	514	754	09/21/87
_____	4,929,602	05/29/1990	Harker et al.	514	18	11/22/88
_____	4,962,091	10/09/1990	Eppstein et al.	514	2	05/23/86
_____	4,968,350	11/06/1990	Bindschaedler et al.	106	170	04/01/88
_____	4,973,755	11/27/1990	Grafe et al.	564	324	04/19/88
_____	4,990,538	02/05/1991	Harris et al.	514	648	08/23/89
_____	4,994,033	02/19/1991	Shockey et al.	604	101	05/29/89
_____	4,996,225	02/26/1991	Toivola et al.	514	428	05/25/83
_____	4,997,652	03/05/1991	Wong	424	428	05/31/89
_____	5,008,279	04/16/1991	Franckowiak et al.	514	345	10/27/88
_____	5,009,659	04/23/1991	Hamlin et al.	606	159	10/30/89
_____	5,015,666	05/14/1991	Magarian et al.	514	754	09/22/89
_____	5,026,537	06/25/1991	Daddona et al.	424	1.1	05/06/89
_____	5,032,679	07/16/1991	Brandley et al.	536	21	08/31/89
_____	5,043,335	08/27/1991	Kleinschroth et al.	514	211	06/23/90
_____	5,047,431	09/10/1991	Schickaneder et al.	514	648	05/14/90
_____	5,049,132	09/17/1991	Schaffer et al.	604	101	01/08/90
_____	5,053,033	10/01/1991	Clarke et al.	606	3	10/10/90

Examiner

Date Considered

*Substitute Disclosure Statement Form (PTO-1449)

**EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449*	Atty. Docket No.: 295.009US4	Serial No. Unknown
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Applicant: David J. Grainger et al.	
	Filing Date: Herewith	Group: Unknown

U.S. PATENT DOCUMENTS

**Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
	5,059,166	11/22/1991	Fischell et al.	600	3	12/11/89
	5,066,789	11/19/1991	Srinivasan et al.	530	388	09/29/89
	5,075,321	12/24/1991	Schreiber	514	317	02/24/88
	5,098,903	03/24/1992	Magarian et al.	514	255	11/06/89
	5,102,402	04/07/1992	Dror et al.	604	265	01/04/91
	5,108,989	05/28/1992	Amento et al.	514	12	04/04/90
	5,112,305	05/12/1992	Barath et al.	704	96	10/16/90
	5,114,719	05/19/1992	Sabel et al.	424	422	09/14/89
	5,116,864	05/26/1992	March et al.	514	455	04/09/91
	5,120,535	06/09/1992	Marquardt et al.	424	85.5	05/04/87
	5,140,012	08/18/1992	McGovern et al.	514	19	05/31/90
	5,166,143	11/24/1992	Ondetti et al.	514	89	06/13/91
	5,171,217	12/15/1992	March et al.	604	53	02/28/91
	5,176,617	01/05/1993	Fischell et al.	600	3	11/21/91
	5,180,366	01/19/1993	Woods	604	96	10/10/90
	5,185,260	02/09/1993	Crissman et al.	435	244	08/29/91
	5,189,046	02/23/1993	Burch et al.	514	330	08/14/90
	5,189,212	02/23/1993	Ruenitz	562	468	09/07/90
	5,192,525	03/09/1993	Yang et al.	424	11	06/28/91
	5,199,939	04/06/1993	Dake et al.	600	3	02/23/90
	5,208,019	05/05/1993	Hanson et al.	424	85	09/27/89
	5,213,576	05/25/1993	Abiuso et al.	604	96	06/11/91
	5,213,580	05/25/1993	Slepian et al.	623	1	03/25/92
	5,216,126	06/01/1993	Cox et al.	530	350	06/19/91
	5,219,548	06/15/1993	Yang et al.	424	1	10/01/90
	5,221,620	06/22/1993	Purchio et al.	435	69	12/05/89
	5,226,430	07/13/1993	Spears et al.	128	898	05/24/91
	5,229,495	04/20/1993	Ichijo et al.	530	350	06/18/91
	5,232,444	08/03/1993	Just et al.	604	96	02/25/91
	5,238,714	08/24/1993	Wallace et al.	427	213	10/02/90
	5,238,950	08/24/1993	Clader et al.	514	360	12/17/91
	5,242,397	09/07/1993	Barath et al.	604	96	01/02/92
	5,248,764	09/28/1993	Flanagan et al.	530	324	02/27/92
	5,254,594	10/19/1993	Niikura et al.	514	648	04/08/92
	5,268,358	12/07/1993	Fretto et al.	514	12	05/06/91
	5,270,047	12/14/1993	Kauffman et al.	424	422	11/21/91
	5,280,016	01/18/1994	Conrad et al.	514	56	09/03/91
	5,280,109	01/18/1994	Miyazono et al.	530	399	01/27/92
	5,282,785	02/01/1994	Shapland et al.	604	21	10/05/92
	5,283,257	02/01/1994	Gregory et al.	514	458	07/10/92
	5,284,763	02/08/1994	Derynk et al.	435	240	03/04/92
	5,284,869	02/08/1994	Bisaccia et al.	514	455	12/17/91
	5,288,711	02/22/1994	Mitchell et al.	514	56	04/28/92
	5,296,492	03/22/1994	Shiozawa et al.	514	337	06/03/92

Examiner

Date Considered

*Substitute Disclosure Statement Form (PTO-1449)

**EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449*	Atty. Docket No.: 295.009US4	Serial No. Unknown
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Applicant: David J. Grainger et al.	
	Filing Date: Herewith	Group: Unknown

U.S. PATENT DOCUMENTS

**Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
	5,304,325	04/19/1994	Kaufman et al.	252	312	11/13/91
	5,304,541	04/19/1994	Purchio et al.	514	12	03/14/91
	5,308,622	05/03/1994	Casscells et al.	424	422	07/16/92
	5,308,862	05/03/1994	Ohlstein et al.	514	411	03/05/93
	5,314,679	05/24/1994	Lewis et al.	424	9	12/22/92
	5,316,766	05/31/1994	Baldus et al.	424	94	02/06/90
	5,324,736	06/28/1994	Magarin et al.	514	317	08/16/93
	5,326,757	07/05/1994	Demopoulos	514	167	08/18/93
	5,328,471	07/12/1994	Slepian	604	101	08/04/93
	5,332,584	07/26/1994	Scher et al.	424	408	12/09/91
	5,340,925	08/23/1994	Lioubin et al.	530	395	06/17/92
	5,346,702	09/13/1994	Na et al.	424	490	12/04/92
	5,346,993	09/13/1994	Miyazono et al.	530	399	07/15/93
	5,354,562	10/11/1994	Platz et al.	424	489	01/16/93
	5,354,774	10/11/1994	Deckelbaum et al.	514	455	12/24/92
	5,354,801	10/11/1994	O'Toole et al.	524	461	08/12/93
	5,356,713	10/18/1994	Charmot et al.	428	407	06/01/93
	5,362,424	11/08/1994	Lee et al.	264	4.3	10/10/91
	5,364,632	11/15/1994	Benita et al.	424	450	03/09/93
	5,380,716	01/10/1995	Conrad et al.	514	56	12/28/92
	5,384,332	01/24/1995	Fontana	514	648	05/11/94
	5,385,935	01/31/1995	Tamai et al.	514	535	09/07/93
	5,389,670	02/14/1995	Fontana	514	443	12/21/93
	5,391,557	02/21/1995	Cullinan et al.	514	324	10/15/93
	5,393,763	02/28/1995	Black et al.	514	333	01/12/94
	5,393,772	02/28/1995	Yue et al.	514	410	11/24/93
	5,393,785	02/28/1995	Labrie et al.	514	622	07/14/92
	5,395,842	03/07/1995	Labrie et al.	514	320	12/02/91
	5,401,730	03/28/1995	Sauvage et al.	514	165	07/06/90
	5,418,252	05/23/1995	Williams	514	443	10/15/93
	5,423,885	06/13/1995	Williams	623	1	07/14/93
	5,424,331	06/13/1995	Shlyankevich	514	456	06/10/94
	5,426,123	06/20/1995	Fontana	514	651	05/11/94
	5,429,634	07/04/1995	Narcisco Jr.	604	890.1	09/09/93
	5,434,166	07/18/1995	Glasebrook	514	317	08/22/94
	5,436,243	07/25/1995	Sachs et al.	514	231	11/17/93
	5,439,923	08/08/1995	Cullinan	514	324	12/21/93
	5,439,931	08/08/1995	Sales	514	443	12/21/93
	5,441,947	08/15/1995	Dodge et al.	514	179	08/25/93
	5,441,964	08/15/1995	Bryant et al.	514	324	10/15/93
	5,441,965	08/15/1995	Sall et al.	514	324	12/21/93
	5,441,986	08/15/1995	Thompson	514	648	07/19/94
	5,444,164	08/22/1995	Purchio et al.	536	23.5	05/04/92
	5,446,053	08/29/1995	Keohane	514	324	12/21/93

Examiner	Date Considered
----------	-----------------

*Substitute Disclosure Statement Form (PTO-1449)

**EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449*	Atty. Docket No.: 295.009US4	Serial No. Unknown
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Applicant: David J. Grainger et al.	
	Filing Date: Herewith	Group: Unknown

U.S. PATENT DOCUMENTS

**Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
	5,447,941	09/05/1995	Zuckerman	514	324	12/21/93
	5,453,442	09/26/1995	Bryant et al.	514	408	02/18/94
	5,455,275	10/03/1995	Fontana	514	648	05/11/94
	5,457,113	10/10/1995	Cullinan et al.	514	319	10/15/93
	5,457,116	10/10/1994	Black et al.	514	324	10/15/93
	5,457,117	10/10/1995	Black et al.	514	337	10/26/94
	5,458,568	10/17/1995	Racchini et al.	604	19	09/17/93
	5,462,937	10/31/1995	Cullinan et al.	514	212	04/14/95
	5,466,810	11/14/1995	Godfrey	546	202	06/10/94
	5,468,746	11/21/1995	Casagrande et al.	514	235.5	06/21/91
	5,470,883	11/28/1995	Stromberg	514	648	05/23/94
	5,472,985	12/05/1995	Grainger et al.	514	651	09/02/94
	5,478,847	12/26/1995	Draper	514	333	03/02/94
	5,480,888	01/02/1996	Kodama et al.	514	320	06/11/94
	5,480,904	01/02/1996	Bryant et al.	514	443	10/28/93
	5,482,949	01/09/1996	Black et al.	514	324	03/19/93
	5,482,950	01/09/1996	Bryant et al.	514	324	10/15/93
	5,484,795	01/16/1996	Bryant et al.	514	319	09/20/94
	5,484,796	01/16/1996	Bryant et al.	514	319	04/21/95
	5,484,798	01/16/1996	Bryant et al.	514	324	09/20/94
	5,484,808	01/16/1996	Grinnell	514	443	02/09/95
	5,489,587	02/06/1996	Fontana	514	233.5	01/20/95
	5,491,159	02/13/1996	Malamas	514	374	08/30/94
	5,491,173	02/13/1996	Toivola et al.	514	648	05/25/83
	5,492,921	02/20/1996	Bryant et al.	514	324	09/20/94
	5,492,922	02/20/1996	Palkowitz	514	324	02/28/95
	5,492,926	02/20/1996	Cullinan et al.	514	422	10/15/93
	5,492,927	02/20/1996	Gitter et al.	514	443	12/21/93
	5,496,828	03/05/1996	Cullinan	514	324	08/22/94
	5,498,775	03/12/1996	Novak et al.	514	25	11/07/94
	5,508,292	04/16/1996	Sall et al.	514	324	04/14/95
	5,510,370	04/23/1996	Hock et al.	514	443	03/06/95
	5,516,781	05/14/1996	Morris et al.	514	291	05/12/94
	5,516,807	05/14/1996	Hupe et al.	514	673	10/25/94
	5,519,042	05/21/1996	Morris et al.	514	378	01/13/94
	5,521,171	05/28/1996	Sorenson	514	188	03/24/95
	5,521,191	05/28/1996	Greenwald	514	262	10/17/94
	5,521,198	05/28/1996	Zuckerman	514	324	12/21/93
	5,527,337	06/18/1996	Stack et al.	606	198	02/01/91
	5,534,527	07/09/1996	Black et al.	514	333	04/14/95
	5,541,174	07/30/1996	Sorenson	514	186	01/18/95
	5,545,409	08/13/1996	Laurencin et al.	424	426	04/05/94
	5,545,569	08/13/1996	Grainger et al.	436	518	05/25/95
	5,552,415	09/03/1996	May	514	324	12/21/93

Examiner

Date Considered

*Substitute Disclosure Statement Form (PTO-1449)

**EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449*	Atty. Docket No.: 295.009US4	Serial No. Unknown
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Applicant: David J. Grainger et al.	
	Filing Date: Herewith	Group: Unknown

U.S. PATENT DOCUMENTS

**Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
_____	5,567,713	10/22/1996	Cullinan et al.	514	324	01/09/95
_____	5,563,054	10/08/1996	Briggs et al.	435	127	03/31/95
_____	5,571,714	11/05/1996	Dasch et al.	435	240.27	12/22/88
_____	5,574,047	11/12/1996	Bumol et al.	514	324	12/21/93
_____	5,595,722	01/21/1997	Grainger et al.	424	9.2	06/07/95
_____	5,597,578	01/28/1997	Brown et al.	424	422	09/11/89
_____	5,599,844	02/04/1997	Grainger et al.	514	651	09/15/95
_____	5,610,166	03/11/1997	Singh	514	324	03/22/95
_____	5,622,975	04/22/1997	Singh et al.	514	324	06/01/95
_____	5,639,274	06/17/1997	Fischell et al.	604	96	06/02/95
_____	5,658,927	08/19/1997	Magarian et al.	514	315	06/07/95
_____	5,681,835	10/28/1997	Willson	514	237.5	04/25/94
_____	5,686,467	11/11/1997	Bumol et al.	514	324	03/15/95
_____	5,726,186	03/10/1998	Grese	514	321	08/13/96
_____	5,770,609	06/23/1998	Grainger et al.	514	319	06/07/95
_____	5,847,007	12/08/1998	Grainger et al.	514	651	05/12/94
_____	5,945,456	08/31/1999	Grainger et al.	514	651	11/06/97
_____	Re. 32,944	06/06/1989	Harita et al.	562	455	06/01/77

FOREIGN PATENT DOCUMENTS

**Examiner Initial	Document Number	Date	Country	Class	Subclass	Translation Yes No
_____	0 054 168	06/23/1982	European	C07C	93/06	Abstract
_____	0 095 875	12/07/1983	European	C07C	33/26	
_____	0 260 066	03/16/1988	European	C07C	217/54	
_____	0 365 863	05/02/1990	European	C07D	413/54	
_____	0 374 044	06/20/1990	European	C12N	15/16	
_____	0 451 202	10/16/1991	European	A61K	9/70	
_____	0 542 679	05/19/1993	European	C12N	15/12	
_____	0 577 215	01/05/1993	European	A61K	9/14	
_____	0 584 952	03/02/1994	European	A61K	31/445	
_____	0 588 518	02/23/1994	European	A61K	31/165	
_____	0 606 613	07/20/1994	European	G01N	33/531	
_____	0 622 076	11/02/1994	European	A61K	31/165	
_____	0 629 697	12/21/1994	European	C12N	15/63	
_____	0 635 270	01/25/1995	European	A61K	38/29	
_____	0 664 121	07/26/1995	European	A61K	31/445	
_____	0 664 122	07/26/1995	European	A61K	31/445	
_____	0 670 162	09/06/1995	European	A61K	31/445	
_____	0 674 903	10/04/1995	European	A61K	31/445	
_____	0 675 121	10/04/1995	European	C07D	333/56	
_____	0 699 673	03/06/1996	European	C07D	333/56	
_____	1 015 787	01/05/1966	Great Britain			

Examiner	Date Considered
----------	-----------------

*Substitute Disclosure Statement Form (PTO-1449)

**EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449*	Atty. Docket No.: 295.009US4	Serial No. Unknown
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Applicant: David J. Grainger et al.	
	Filing Date: Herewith	Group: Unknown

FOREIGN PATENT DOCUMENTS

**Examiner Initial	Document Number	Date	Country	Class	Subclass	Translation	
						Yes	No
_____	2 273 873	06/07/1994	Great Britain	A61K	31/48		
_____	4 320 896	01/05/1995	Germany	A61K	31/40		
_____	4 320 898	01/05/1995	Germany	A61K	31/135		
_____	4 401 554	08/18/1994	Germany	A61K	31/135		
_____	85/00107	01/17/1985	PCT	A61K	31/13		
_____	88/10259	12/29/1988	PCT	C07D	313/00		
_____	90/01969	03/08/1990	PCT	A61M	29/00		
_____	90/13293	11/15/1990	PCT	A61K	31/40		
_____	91/15219	10/14/1991	PCT	A61K	37/00		
_____	91/15222	10/17/1991	PCT	A61K	37/02		
_____	92/06068	04/16/1992	PCT	C07C	217/18		
_____	92/08480	05/29/1992	PCT	A61K	37/36		
_____	92/11890	07/23/1992	PCT	A61M	25/00		
_____	92/11895	07/23/1992	PCT	A61K	31/00		
_____	92/18546	10/29/1992	PCT	C08B	37/10		
_____	92/19273	11/12/1992	PCT	A61K	49/02		
_____	92/19612	11/12/1992	PCT	C07D	333/38		
_____	92/21363	12/10/1992	PCT	A61K	37/02		
_____	93/07748	04/29/1993	PCT	A01N	43/16		
_____	93/09228	05/13/1993	PCT	C12N	15/12		
_____	93/09790	05/27/1993	PCT	A61K	31/70		
_____	93/10808	06/10/1993	PCT	A61K	37/02		
_____	93/11757	06/24/1993	PCT	A61K	31/135		
_____	93/16724	09/02/1993	PCT	A61K	39/00		
_____	93/19746	10/14/1993	PCT	A61K	31/135		
_____	94/04164	03/03/1994	PCT	A61K	31/795		
_____	94/04178	03/03/1994	PCT	A61K	37/02		
_____	94/07529	04/14/1994	PCT	A61K	39/00		
_____	94/08604	04/28/1994	PCT	A61K	37/00		
_____	94/08605	04/28/1994	PCT	A61K	37/00		
_____	94/09764	05/11/1994	PCT	A61K	31/00		
_____	94/09812	05/11/1994	PCT	A61K	37/36		
_____	94/10187	05/11/1994	PCT	C07H	21/02		
_____	94/15589	07/21/1994	PCT	A61K	9/50		
_____	94/15590	07/21/1994	PCT	A61K	9/51		
_____	94/15646	07/21/1994	PCT	A61K	48/00		
_____	94/16706	08/04/1994	PCT	A61K	31/535		
_____	94/17786	08/18/1994	PCT	A61K	9/16		
_____	94/18967	09/01/1994	PCT	A61K	31/415		
_____	94/18968	09/01/1994	PCT	A61K	31/415		
_____	94/19000	09/01/1994	PCT	A61K	37/02		
_____	94/19001	09/01/1994	PCT	A61K	37/02		
_____	94/19003	09/01/1994	PCT	A61K	37/02		
_____	94/20096	09/15/1994	PCT	A61K	31/40		
_____	94/20097	09/15/1994	PCT	A61K	31/40		

Examiner	Date Considered
----------	-----------------

*Substitute Disclosure Statement Form (PTO-1449)

**EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449*	Atty. Docket No.: 295.009US4	Serial No. Unknown
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Applicant: David J. Grainger et al.	
	Filing Date: Herewith	Group: Unknown

FOREIGN PATENT DOCUMENTS

**Examiner Initial	Document Number	Date	Country	Class	Subclass	Translation	
						Yes	No
	94/20126	09/15/1994	PCT	A61K	37/02		
	94/20127	09/15/1994	PCT	A61K	37/02		
	94/21679	09/29/1994	PCT	C07K	13/00		
	94/23068	10/13/1994	PCT	C12Q	1/68		
	94/23699	10/27/1994	PCT	A61K	9/14		
	94/25588	11/10/1994	PCT	C12N	15/11		
	94/26291	11/24/1994	PCT	A61K	37/02		
	94/26303	11/24/1994	PCT	A61K	39/00		
	94/26888	10/06/1995	PCT	C12N	15/11		
	94/28721	12/22/1994	PCT	A01N	43/42		
	95/03036	02/02/1995	PCT	A61K	9/16		
	95/04544	02/16/1995	PCT	A61K	38/22		
	95/10611	04/20/1995	PCT	C12N	15/12		
	95/19987	07/27/1995	PCT	C07H	21/00		
	95/30900	11/16/1995	PCT	G01N	33/50		
	96/01102	01/18/1996	PCT	A61K	9/06		
	96/07402	03/14/1996	PCT	A61K	31/075		
	96/15224	05/23/1996	PCT	C12N	5/00		
	96/24356	08/15/1996	PCT	A61K	31/55		
	96/36349	11/21/1996	PCT	A61K	38/17		

OTHER DOCUMENTS

(Including Author, Title, Date, Pertinent Pages, Etc.)

**Examiner Initial	
	"Breast Cancer Prevention Trial Should Resume, ODAC Says", <u>The Breast Cancer Letter</u> , 20 4-5, (1994).
	"Coronary Artery Disease: Restenosis and Reocclusion After Surgical and Nonsurgical Interventions, Part I", <u>Drug & Market Development</u> , 5, 121-129 (1994).
	"Nolvadex Tamoxifene Citrate", <u>ICI Pharma</u> , 64033-02, Rev. 1/07/92.
	"Prevention of Coronary Heart Disease", In: <u>Avery's Drug Treatment -- Principles and Practice of Clinical Pharmacology and Therapeutics</u> , Speight, T. M., (ed.), Williams and Wilkins, Baltimore, 594-595 (1987).
	"Shiga Medical Center for Adult Diseases, "The Impact of Tranilast on Restenosis Following Coronary Angioplasty: The Tranilast Restenosis Following Angioplasty Trial (TREAT)", <u>Circulation</u> , 90, I-82, Abstract No. 0 (1988).
	AinMelk, Y., et al., "Tamoxifen Citrate Therapy in Male Fertility", <u>Fertility and Sterility</u> , 48, 113-117 (1987).

Examiner

Date Considered

*Substitute Disclosure Statement Form (PTO-1449)

**EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449*	Atty. Docket No.: 295.009US4	Serial No. Unknown
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Applicant: David J. Grainger et al.	
	Filing Date: Herewith	Group: Unknown

OTHER DOCUMENTS

(Including Author, Title, Date, Pertinent Pages, Etc.)

**Examiner
Initial

	Allemann, et al., "Distribution, Kinetics, and Elimination of Radioactivity after Intravenous and Intramuscular Injection of ¹⁴ C-Savoxepoine Loaded Poly (D,L-lactic acid) Nanospheres to Rats", <u>J. Controlled Release</u> , <u>29</u> , 97-104 (1994).
	Allemann, E., et al., "Drug Loaded Poly(lactic acid) Nanoparticles Produced by a Versible Salting-out Process: Purification of an Injectable Dosage Form", <u>Eur. J. Pharm. Biopharm</u> , <u>39</u> , 13-18 (1993).
	Anderson, et al., "Effects of Acetate Dialysate on Transforming Growth Factor B1-interleukin and B2-micoglobulin Plasma Levels", <u>Kidney International</u> , <u>40</u> , 1110-1117 (1991).
	Anker, et al., "Plasma Levels of the Atherogenic Amino Acid Homocysteine in Post-Menopausal Women with Breast Cancer Treated with Tamoxifen", <u>Int. J. Cancer</u> , <u>60</u> , 365-368 (1995).
	Assoian, et al., "Type Beta Transforming Growth Factor in Human Platelets: Release During Platelet Degranulation and Action on Vascular Smooth Muscle Cells", <u>J. Cell. Biol.</u> , <u>102</u> , 1217-1223 (1986).
	Attwood, et al., "A Light Scattering Study on Oil-in-Water Microemulsions", <u>Int'l J. Pharm</u> , <u>52</u> , 165-171 (1989).
	Bagdade, J.D., et al., "Effects of Tamoxifen Treatment on Plasma Lipids and Lipoprotein Lipid Composition", <u>J. Clinical Endocrinology and Metabolism</u> , <u>70</u> , 1132-1135 (1990).
	Barath, et al., "Low Dose of Antitumor Agents Prevents Smooth Muscle Cell Proliferation After Endothelial Injury", <u>JACC</u> , <u>13</u> , 252A (1989).
	Barinaga, "Gene Therapy for Clogged Arteries Passes to Test in Pigs", <u>Science</u> , <u>265</u> , 738 (1994).
	Beck, et al., "Poly(DL-lactide-co-glycolide)/norethisterone microcapsules: an injectible biodegradable contraceptive", <u>Biol. Reprod.</u> , <u>28</u> , 186-195 (1983).
	Benita, et al., "Submicron Emulsions as Colloidal Drug Carriers for Intravenous Administration: Comprehensive Physicochemical Characterization", <u>J. of Pharmaceutical Sciences</u> , <u>82</u> , 1069-1079 (1993).
	Bertelli, et al., "Adjuvant Tamoxifen in Primary Breast Cancer: Influence on Plasma Lipids and Antithrombin III Levels", <u>Breast Cancer Res. and Treatment</u> , <u>12</u> , 307-310 (1988).

Examiner

Date Considered

*Substitute Disclosure Statement Form (PTO-1449)

**EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449*	Atty. Docket No.: 295.009US4	Serial No. Unknown
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Applicant: David J. Grainger et al.	
	Filing Date: Herewith	Group: Unknown

OTHER DOCUMENTS

(Including Author, Title, Date, Pertinent Pages, Etc.)

**Examiner
Initial

	Bier, J.D., et al., "Arterial Remodeling: Importance in Primary Versus Restenotic Lesions", <u>JACC</u> , Abstract No. 875-96, 139A (1994).
	Bluming, "Hormone Replacement Therapy: Benefits and Risks for the General Postmenopausal Female Population and for Women with a History of Previously Treated Breast Cancer", <u>Seminars in Oncology</u> , <u>20</u> , 662-674 (1993).
	Brott, B.C., et al., "Vessel Remodeling After Angioplasty: Comparative Anatomic Studies", <u>JACC</u> , Abstract No. 875-43, 138A (1994).
	Bruengger, et al., "Smooth Muscle Cell of the Canine Prostate in Spontaneous Benign Hyperplasia, Steriod Induced Hyperplasia and Estrogen or Tamoxifen Treated Dogs", <u>J. Urology</u> , <u>130</u> , 1208-1210 (1983).
	Bruning, et al., "Tamoxifen, Serum Lipoproteins and Cardiovascular Risk", <u>Br. J. Cancer</u> , <u>58</u> , 497-499 (1988).
	Butta, A., et al., "Induction of Transforming Growth Factor Betal in Human Breast Cancer in Vivo Following Tamoxifen Treatment", <u>Cancer Research</u> , <u>52</u> , 4261-4164 (1992).
	Chander, et al., "Pyrrolidino-4-iodotamoxifen and 4-iodotamoxifen, New Analogues of the Antiestrogen Tamoxifen for the Treatment of Breast Cancer", <u>Cancer Res.</u> , <u>51</u> , 5851-5858 (1991).
	Chao, et al., "Altered Cytokine Release in Peripheral Blood Mononuclear Cell Cultures from Patients with the Chronic Fatigue Syndrome", <u>Cytokine</u> , <u>3</u> , 292-298 (1991).
	Chapman, G.D., et al., "A Bioabsorbable Stent: Initial Experimental Results", <u>Supplement III Circulation</u> , <u>82</u> , Abstract No. 0283, III-72, (1990).
	Charlier, et al., "Tamoxifen in the Treatment of Breast Cancer", <u>J. Gynecol. Obstet Biol. Reprod.</u> , <u>23</u> , 751-756 (1994).
	Chauhan, A., et al., "Activation of Transforming Growth Factor-beta is Inversely Correlated with Three Major Risk Factors for Coronary Artery Disease: Lipoprotein(a), LDL-Cholesterol and Plasminogen Activator Inhibitor-1", <u>Circulation</u> , <u>90</u> , 67th Scientific Sessions, Abstract No. 3354, I-623 (1994).
	Clowes, A.W., et al., "Kinetics of Cellular Proliferation after Arterial Injury -- I. Smooth Muscle Growth in the Absence of Endothelium", <u>Laboratory Investigation</u> , <u>49</u> , 327-333 (1983).

Examiner

Date Considered

*Substitute Disclosure Statement Form (PTO-1449)

**EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449*	Atty. Docket No.: 295.009US4	Serial No. Unknown
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Applicant: David J. Grainger et al.	
	Filing Date: Herewith	Group: Unknown

OTHER DOCUMENTS

(Including Author, Title, Date, Pertinent Pages, Etc.)

**Examiner
Initial

	Clowes, A.W., et al., "Kinetics of Cellular Proliferation after Arterial Injury -- III. Endothelium and Smooth Muscle Growth in Chronically Denuded Vessels", <u>Laboratory Investigation</u> , <u>54</u> , 295-303 (1986).
	Clowes, A.W., et al., "Significance of Quiescent Smooth Muscle Migration in the Injured Rat Carotid Artery", <u>Circulation Research</u> , <u>56</u> , 139-145 (1985).
	Cohen, et al., "Controlled Delivery Systems for Proteins Based on Poly(lactic/glycolic acid) Microspheres", <u>Pharmaceutical Research</u> , <u>8</u> , 713-720 (1991).
	Colletta, A.A., et al., "Anti-oestrogens induce the secretion of active transforming growth factor beta from human fetal fibroblasts", <u>Br. J. Cancer</u> , <u>62</u> , 405-409 (1990).
	Coombes, R.C., et al., "Idoxifene: Report of a Phase I Study in Patients with Metastatic Breast Cancer", <u>Cancer Research</u> , <u>55</u> , 1070-1074 (1995).
	Cotton, P., "Restenosis Trials Suggest Role for Remodeling", <u>JAMA</u> , <u>271</u> , 1302-1305 (1994).
	Cowsar, et al., "Poly(actide-co-glycolide) Microcapsules for Controlled Release of Steroids", <u>Methods Enzymology</u> , <u>112</u> , 101-116 (1985).
	Craig, et al., "Anticoagulant Drugs", In Modern Pharmacology, Little, Brown and Co., Boston, 399 (1982).
	Currier, J.W., et al., "Restenosis After Percutaneous Transluminal Coronary Angioplasty: Have We Been Aiming at the Wrong Target?", <u>JACC</u> , <u>25</u> , 516-520 (1995).
	Danielpour, "Improved Sandwich Enzyme-linked Immunosorbent Assays Transforming Growth Factor B1", <u>J. Immunol. Methods</u> , <u>158</u> , 17-25 (1993).
	Danielpour, D., et al., "Evidence for Differential Regulation of TGF-Beta1 and TGF-Beta2 Expression in Vivo by Sandwich Enzyme-linked Immunosorbent Assays", <u>Annals N.Y. Acad. Sci.</u> , <u>593</u> , 300-302 (1990).
	Danielpour, D., et al., "Immunodetection and Quantitation of the Two Forms of Transforming Growth Factor-Beta (TGF-Beta1 and TGF-Beta2) Secreted by Cells in Culture", <u>J. Cell. Physiol.</u> , <u>138</u> , 79-86 (1989).
	Dasch, J.R., et al., "Capture Immunoassays Specific for TGF-Beta1 and TGF-Beta2: Use in Pharmacokinetic Studies", <u>Annals N.Y. Acad. Sci.</u> , <u>593</u> , 303-305 (1990).

Examiner

Date Considered

*Substitute Disclosure Statement Form (PTO-1449)

**EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449*	Atty. Docket No.: 295.009US4	Serial No. Unknown
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Applicant: David J. Grainger et al.	
	Filing Date: Herewith	Group: Unknown

OTHER DOCUMENTS

(Including Author, Title, Date, Pertinent Pages, Etc.)

**Examiner
Initial

	Davies, A.M., et al., "Peroxidase Activation of Tamoxifen and Toremifene Resulting in DNA Damage and Covalently Bound Protein Adducts", <u>Carcinogenesis</u> , <u>16</u> , 539-545 (1995).
	Di Mario, C., et al., "Is the Mechanism of Restenosis Device-Independent? Serial Assessment with Intracoronary Ultrasound", <u>Circulation</u> , <u>90</u> , Abstract No. 115, I-24 (1994).
	Dimond, P.F., "TGF-Beta Shows Potential as Therapeutic Agent for Macular Holes", <u>Genetic Engineering News</u> , pages 7, 19 (1993).
	Dowsett, M., "New Developments in the Hormonal Treatment of Breast Cancer", In: The Treatment of Cancer: Beyond Chemotherapy, Conference Documentation, The Gloucester Hotel, London, 7 p., (1995).
	Dragan, Y.P., et al., "Comparison of the Effects of Tamoxifen and Toremifene on Liver and Kidney Tumor Promotion in Female Rats", <u>Carcinogenesis</u> , <u>16</u> , 2733-2741 (1995).
	Ebner, et al., "Cloning of a Type I TGF-B Receptor and Its Effect on TGF-B Binding to the Type II Receptor", <u>Science</u> , <u>260</u> , 1344-1348 (1993).
	Edelman, E.R., et al., "Effect of Controlled Adventitial Heparin Delivery on Smooth Muscle Cell Proliferation Following Endothelial Injury", <u>Proc. Natl. Acad. Sci. USA</u> , <u>87</u> , 3773-3777 (1990).
	Eldridge, J.H., et al., "Biodegradable and Biocompatible Poly(DL-Lactide-Co-Glycolide) Microspheres as an Adjuvant for Staphylococcal Enterotoxin B Toxoid Which Enhances the Level of Toxin-Neutralizing Antibodies", <u>Infection and Immunity</u> , <u>59</u> , 2978-2986 (1991).
	Fanelli, C., et al., "Restenosis Following Coronary Angioplasty", <u>American Heart Journal</u> , <u>119</u> , 357-368 (1990).
	Farhat, et al., "In Vitro Effect of Oestradiol on Thymidine Uptake in Pulmonary Vascular Smooth Muscle Cell: Role of the Endothelium.", <u>Br. J. Pharmacol.</u> , <u>107</u> , 679-683 (1992).
	Faxon, D.P., et al., "Restenosis Following Transluminal Angioplasty in Experimental Atherosclerosis", <u>Arteriosclerosis</u> , <u>4</u> , 189-195 (1984).
	Fischell, T.A., et al., "Low-Dose, beta-Particle Emission From 'Stent' Wire Results in Complete, Localized Inhibition of Smooth Muscle Cell Proliferation", <u>Circulation</u> , <u>90</u> , 2956-2963 (1994).

Examiner

Date Considered

*Substitute Disclosure Statement Form (PTO-1449)

**EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449*	Atty. Docket No.: 295.009US4	Serial No. Unknown
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Applicant: David J. Grainger et al.	
	Filing Date: Herewith	Group: Unknown

OTHER DOCUMENTS

(Including Author, Title, Date, Pertinent Pages, Etc.)

**Examiner
Initial

	Fischer, et al., "A Possible Mechanism in Arterial Wall for Mediation of Sex Difference in Atherosclerosis Experimental and Molecular Pathology", <u>Exp. Mol. Pathol.</u> , <u>43</u> , 288-296 (1985).
	Fischman, D.L., et al., "A Randomized Comparison of Coronary-Stent Placement and Balloon Angioplasty in the Treatment of Coronary Artery Disease", <u>The New England Journal of Medicine</u> , <u>331</u> , 496-501 (1994).
	Forrester, J.S., et al., "A Paradigm for Restenosis Based on Cell Biology: Clues for the Development of New Preventive Therapies", <u>JACC</u> , <u>17</u> , 758-769 (1991).
	Frazier-Jessen, et al., "Estrogen Modulation of JE/Monocyte Chemoattractant Protein-1 mRNA Expression in Murine Macrophages", <u>J. Immunol.</u> , <u>154</u> , 1828-1845 (1994).
	Friberg, et al., "Microemulsions and Solubilization by Nonionic Surfactants", <u>Prog. Colloid and Polymer Sci.</u> , <u>56</u> , 16-20 (1975).
	Furr, B.J., et al., "The Pharmacology and Clinical Uses of Tamoxifen", <u>Pharmac. Ther.</u> , <u>25</u> , 127-205 (1984).
	Gasco, et al., "In Vitro Permeation of Azelaic Acid from Viscosized Microemulsions", <u>International Journal of Pharmaceutics</u> , <u>69</u> , 193-196 (1991).
	Gasco, M.R., et al., "Long-acting Delivery Systems for Peptides: Reduced Plasma Testosterone Levels in Male Rats after a Single Injection", <u>Intl. J. of Pharmaceut.</u> , <u>62</u> , 119-123 (1990).
	Gertz, S.D., et al., "Geometric Remodeling Is Not the Principal Pathogenic Process in Restenosis After Balloon Angioplasty", <u>Circulation</u> , <u>90</u> , 3001-3009 (1994).
	Giachelli, et al., "Osteopontin is Elevated During Neointima Formation in Rat Arteries and is a Novel Component of Human Atherosclerosis Plaques", <u>J. Clin. Invest.</u> , <u>92</u> , 1686-1696 (1993).
	Gibbons, G.H., et al., "The Emerging Concept of Vascular Remodeling", <u>New England Journal of Medicine</u> , <u>330</u> , 1431-1438 (1994).
	Glagov, S., "Intimal Hyperplasia, Vascular Modeling, and the Restenosis Problem", <u>Circulation</u> , <u>89</u> , 2888-2891 (1994).
	Glagov, S., et al., "Compensatory Enlargement of Human Atherosclerotic Coronary Arteries", <u>New England Journal of Medicine</u> , <u>316</u> , 1371-1375 (1987).

Examiner

Date Considered

*Substitute Disclosure Statement Form (PTO-1449)

**EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449*	Atty. Docket No.: 295.009US4	Serial No. Unknown
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Applicant: David J. Grainger et al.	
	Filing Date: Herewith	Group: Unknown

OTHER DOCUMENTS

(Including Author, Title, Date, Pertinent Pages, Etc.)

**Examiner
Initial

	Goldman, et al., "Influence of Pressure on Permeability of Normal and Diseased Muscular Arteries to Horseradish Peroxidase.", <u>Atherosclerosis</u> , <u>65</u> , 215-225 (1987).
	Grainger, D.J., et al., "A Large Accumulation of Non-Muscle Myosin Occurs at First Entry into M Phase in Rat Vascular Smooth-Muscle Cells.", <u>Biochemical Journal</u> , <u>277</u> , 145-151 (1991).
	Grainger, D.J., et al., "A Pivotal Role for TGF-Beta in Atherogenesis?", <u>Biol. Rev.</u> , <u>70</u> , 571-596 (1995).
	Grainger, D.J., et al., "Activation of Transforming Growth Factor-beta is Inhibited by Apolipoprotein (a) in vivo", <u>Circulation</u> , <u>90</u> , 67th Scientific Session, Abstract No. 3353, I-623 (1994).
	Grainger, D.J., et al., "Activation of Transforming Growth Factor-beta is Inhibited in Transgenic Apolipoprotein(a) Mice", <u>Nature</u> , <u>370</u> , 460-462 (1994).
	Grainger, D.J., et al., "Active and Acid-Activatable TGF-beta in Human Sera, Platelets and Plasma", <u>Clinica Chimica Acta.</u> , <u>235</u> , 11-31 (1995).
	Grainger, D.J., et al., "Active TGF-beta is Depressed Five-Fold in Triple Vessel Disease Patients Compared with Syndrome X Patients", <u>Journal of Cellular Biochemistry</u> , <u>18A</u> , Abstract No. E111, 267 (1994).
	Grainger, D.J., et al., "Active Transforming Growth Factor-beta is Depressed in Patients with Three Vessel Coronary Artery Disease", <u>Circulation</u> , <u>90</u> , 67th Scientific Sessions, Abstract No. 2754, I-512 (1994).
	Grainger, D.J., et al., "Effect of Tamoxifen in the Rat Carotid Injury Model In Vivo", Manuscript in Preparation, (1996).
	Grainger, D.J., et al., "Heparin Decreases the Rate of Proliferation of Rat Vascular Smooth Muscle Cells by Releasing Transforming Growth Factor beta-like Activity from Serum", <u>Cardiovascular Research</u> , <u>27</u> , 2238-2247 (1993).
	Grainger, D.J., et al., "Hexamethylenebisacetamide Selectively Inhibits the Proliferation of Human and Rat Vascular Smooth-Muscle Cells", <u>Biochemical Journal</u> , <u>283</u> , 403-408 (1992).
	Grainger, D.J., et al., "Mitogens for Adult Rat Aortic Vascular Smooth Muscle Cells in Serum-Free Primary Culture", <u>Cardiovascular Research</u> , <u>28</u> , 1238-1242 (1994).
	Grainger, D.J., et al., "Proliferation of Human Smooth Muscle Cells Promoted by Lipoprotein(a)", <u>Science</u> , <u>260</u> , 1655-1658 (1993).

Examiner

Date Considered

*Substitute Disclosure Statement Form (PTO-1449)

**EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449*	Atty. Docket No.: 295.009US4	Serial No. Unknown
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Applicant: David J. Grainger et al.	
	Filing Date: Herewith	Group: Unknown

OTHER DOCUMENTS

(Including Author, Title, Date, Pertinent Pages, Etc.)

**Examiner
Initial

	Grainger, D.J., et al., "Release and Activation of Platelet Latent TFG-Beta in Blood Clots During Dissolution with Plasmin", <u>Nature Medicine</u> , <u>1</u> , 932-937 (1995).
	Grainger, D.J., et al., "Tamoxifen Decreases the Rate of Proliferation of Rat Vascular Smooth-Muscle Cells in Culture by Inducing Production of Transforming Growth Factor Beta", <u>Biochem J.</u> , <u>294</u> , 109-112 (1993).
	Grainger, D.J., et al., "Tamoxifen: Teaching an Old Drug New Tricks?", <u>Nature Medicine</u> , <u>2</u> , 381-385 (1996).
	Grainger, D.J., et al., "The Serum Concentration of Active Transforming Growth Factor-beta) is Severly Depressed in Advanced Atherosclerosis", <u>Nature Medicine</u> , <u>1</u> , 74-80 (1995).
	Grainger, D.J., et al., "Transforming Growth Factor beta Decreases the Rate of Proliferation of Rat Vascular Smooth Muscle Cells by Extending the G2 Phase of the Cell Cycle and Delays the Rise in Cyclic AMP Before Entry into M Phase", <u>Biochemical Journal</u> , <u>299</u> , 227-235 (1994).
	Grainger, D.J., et al., "Transforming Growth Factor-beta: The Key to Understanding Lipoprotein(a)?", <u>Current Opinion In Lipidology</u> , <u>6</u> , 81-85 (1995).
	Gref, et al., "Biodegradable Long-Circulating Polymeric Nanoshooeres.", <u>Science</u> , <u>263</u> , 1600-1603 (1994).
	Grey, A.B., et al., "The Effect of the Anti-Estrogen Tamoxifen on Cardiovascular Risk Factors in Normal Postmenopausal Women", <u>J. Clinical Endocrinology and Metabolism</u> , <u>80</u> , 3191-3195 (1995).
	Gylling, H., et al., "Tamoxifen and Toremifene Lower Serum Cholesterol by Inhibition of Delta8-Cholesterol Conversion to Lathosterol in Women with Breast Cancer", <u>Journal of Clinical Oncology</u> , <u>13</u> , 2900-2905 (1995).
	Hall, I.H., et al., "Hypolipidemic Activity of Tetrakis-mu-(trimethylamine-boranecarboxylato)-bis(trimethylamine-carboxyborane)-dicopper(II) in Rodents and Its Effect on Lipid Metabolism", <u>J. Pharmaceut. Sci.</u> , <u>73</u> , 973-977 (1984).
	Hanke, H., et al., "Inhibition of Cellular Proliferation After Experimental Balloon Angioplasty by Low-Molecular-Weight Heparin", <u>Circulation</u> , <u>85</u> , 1548-1556 (1992).

Examiner

Date Considered

*Substitute Disclosure Statement Form (PTO-1449)

**EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449*	Atty. Docket No.: 295.009US4	Serial No. Unknown
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Applicant: David J. Grainger et al.	
	Filing Date: Herewith	Group: Unknown

OTHER DOCUMENTS

(Including Author, Title, Date, Pertinent Pages, Etc.)

**Examiner
Initial

	Harpel, et al., "Plasmin Catalysis Binding of Lipoprotein (A) to Immobilized Fibrinogen and Fibrin.", <u>Proc. Natl. Acad. Sci. USA</u> , <u>86</u> , 3847-3851 (1989).
	Ehrlein, C., et al., "Low-Dose Radiactive Endovascular Stents Prevent Smooth Muscle Cell Proliferation and Neointimal Hyperplasia in Rabbits", <u>Circulation</u> , <u>92</u> , 1570-1575 (1995).
	Ehrlein, C., et al., "Pure Beta-particle-emitting Stents Inhibit Neointima Formation in Rabbits", <u>Circulation</u> , <u>93</u> , 641-645 (1996).
	Heldin, et al., "Demonstration of an Antibody Against Platelet-Derived Growth Factor.", <u>Exp. Cell. Res.</u> , <u>136</u> , 255-261 (1981).
	Heller, et al., "Preparation of Polyacetals by the Reaction of Divinyl Ethers and Polyols.", <u>J. Polymer Science, Polymer Letters Edition</u> , <u>18</u> , 293-297 (1980).
	Henriksson, et al., "Hormonal Regulation of Serum Lp (a) Levels.", <u>J. Clin. Invest.</u> , <u>89</u> , 1166-1171 (1992).
	Hofmann, J., et al., "Enhancement of the Antiproliferative Effect of cis-Diamminedichloroplatinum(II) and Nitrogen Mustard by Inhibitors of Protein Kinase C", <u>Int. J. Cancer</u> , <u>42</u> , 382-388 (1988).
	Holmes, Jr., D.R., "Remodeling Versus Smooth Muscle Cell Hyperplasia.", <u>Restenosis Summit VI</u> , The Cleveland Clinic Foundation, 222-223 (1994).
	Hwang, et al., "Effects of Platelet-Contained Growth Factors (PDGF, EGF, IGF-1, and TGF-B) on DNA Synthesis in Porcine Aortic Smooth Muscle Cells in Culture.", <u>Exp. Cell Res.</u> , <u>200</u> , 358-360 (1992).
	Isner, J.M., "Vascular Remodeling: Honey, I Think I Shrunk the Artery", <u>Circulation</u> , <u>89</u> , 2937-2841 (1994).
	Johnson, et al., "Coronary Atherectomy: Light Microscopic and Immunochemical Study of Excised Tissues", <u>Supp. II Circulation</u> , <u>78</u> , Abstract No. 0327, 11-82 (1988).
	Jordan, et al., "Long-Term Tamoxifen Therapy to Control or to Prevent Breast Cancer: Laboratory Concept to Clinical Trials", <u>Hormones, Cell Biology, and Cancer: Perspectives and Potentials</u> , Alan R. Liss, Inc., 105-123 (1988).
	Kakuta, T., et al., "Differences in Compensatory Vessel Enlargement, Not Intimal Formation, Account for Restenosis After Angioplasty in the Hypercholesterolemic Rabbit Model", <u>Circulation</u> , <u>89</u> , 2809-2815 (1994).

Examiner

Date Considered

*Substitute Disclosure Statement Form (PTO-1449)

**EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449*	Atty. Docket No.: 295.009US4	Serial No. Unknown
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Applicant: David J. Grainger et al.	
	Filing Date: Herewith	Group: Unknown

OTHER DOCUMENTS

(Including Author, Title, Date, Pertinent Pages, Etc.)

**Examiner
Initial

	Kakuta, T., et al., "The Impact of Arterial Remodeling on the Chronic Lumen Size After Angioplasty in the Atherosclerotic Rabbit", <u>JACC</u> , Abstract No. 875-95, 138A (1994).
	Kambic, H., et al., "Biomaterials in Artificial Organs", <u>Chemical & Engineering News</u> , 30, 31-48 (1986).
	Kemp, P.R., et al., "Inhibition of PDGF BB Stimulated DNA Synthesis in Rat Aortic Vascular Smooth Muscle Cells by the Expression of a Truncated PDGF Receptor", <u>FEBS Letters</u> , 336, 119-123 (1993).
	Kemp, P.R., et al., "The Id Gene is Activated by Serum but is Not Required for De-differentiation in Rat Vascular Smooth Muscle Cells", <u>Biochemical Journal</u> , 277, 285-288 (1991).
	Kirschenlohr, H.L., et al., "Adult Human Aortic Smooth Muscle Cells in Culture Produce Active TFG-Beta", <u>Amer. J. Physiol.</u> , 265, C571-C576 (1993).
	Kirschenlohr, H.L., et al., "Proliferation of Human Aortic Vascular Smooth Muscle Cells in Culture is Modulated by Active TGF-Beta", <u>Cardiovascular Research</u> , 29, 848-855 (1995).
	Knabbe, C., et al., "Evidence That Transforming Growth Factor beta is a Hormonally Regulated Negative Growth Factor in Human Breast Cancer Cells", <u>Cell</u> , 48, 417-428 (1987).
	Knabbe, C., et al., "Induction of Transforming Growth Factor-B by the Antiestrogens Droloxifene, Tamoxifen, and Toremifene in MCF-7 Cells", <u>Am. J. Clin. Oncol.</u> , 14, S15-S20 (1991).
	Koff, et al., "Negative Regulation of G1 in Mammalian Cells: Inhibition of Cyclin E-Dependent Kinase by TGF-B.", <u>Science</u> , 260, 536-538 (1993).
	Kotoulas, I.G., et al., "Tamoxifen Treatment in Male Infertility. I. Effect on Spermatozoa", <u>Fertility and Sterility</u> , 61, 911-914 (1994).
	Kovach, J.A., et al., "Serial Intravascular Ultrasound Studies Indicate that Chronic Recoil is an Important Mechanism of Restenosis Following Transcatheter Therapy", <u>JAAC</u> , 21, Abstract No. 835-3, 484A (1993).
	Koyama, N., et al., "Regulation of Smooth Muscle Cells Migration by a New Autocrine Migration Factor and TGF-beta", <u>Circulation</u> , 84, Abstract No. 1829, II-459 (1991).

Examiner

Date Considered

*Substitute Disclosure Statement Form (PTO-1449)

**EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449*	Atty. Docket No.: 295.009US4	Serial No. Unknown
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Applicant: David J. Grainger et al.	
	Filing Date: Herewith	Group: Unknown

OTHER DOCUMENTS

(Including Author, Title, Date, Pertinent Pages, Etc.)

**Examiner
Initial

	Kreuzer, J., et al., "Lipoprotein(a) Displays Increased Accumulation Compared with Low-Density Lipoprotein in the Murine Arterial Wall", <u>Chemistry and Physics of Lipids</u> , <u>67/68</u> , 175-190 (1990).
	Kuntz, R.E., et al., "Defining Coronary Restenosis -- Newer Clinical and Angiographic Paradigms", <u>Circulation</u> , <u>88</u> , 1310-1323 (1993).
	Kunz, L.L., et al., "Efficacy of Cytochalasin B in Inhibiting Coronary Restenosis Caused by Chronic Remodeling After Balloon Trauma in Swine", <u>Journal of the American College of Cardiology</u> , Supplement A, Abstract No. 984-23, 302 (1995).
	Kunz, L.L., et al., "Inhibition of Microfilament Reorganization Following Balloon Angioplasty Decreases Extent of Geometric Remodeling in Restenosis", <u>JACC</u> , 44th Annual Scientific Session, Abstract No. 122292 (1995).
	Kunz, L.L., et al., "Sustained Dilation and Inhibition of Restenosis in a Pig Femoral Artery Injury Model", <u>Circulation</u> , <u>90</u> , 67th Scientific Sessions, Abstract No. 1598, I-297 (1994).
	Labhsetwar, V., "Nanoparticles for site specific delivery of U-86983 in restenosis on pig coronary arteries", <u>Proc. Intern. Symp. Control. Rel. Bioact. Mater.</u> , <u>22</u> , 182-183 (1995).
	Lafont, A.M., et al., "Post-Angioplasty Restenosis in the Atherosclerotic Rabbit: Proliferative Response or Chronic Constriction?", <u>Circulation</u> , <u>88</u> , 66th Scientific Sessions, Abstract No. 2806, I-521 (1993).
	Laird, J., et al., "Inhibition of Neointimal Proliferation with Low-dose Irradiation from a Beta-particle-emitting Stent", <u>Circulation</u> , <u>93</u> , 529-536 (1996).
	Lambert, C.R., et al., "Local Drug Delivery Catheters: Functional Comparison of Porous and Microporous Designs", <u>Coronary Artery Disease</u> , <u>4</u> , 469-475 (1993).
	Langbein, W., "Too Many Drugs, Too Little Value in CV Conditions", <u>In Vivo</u> , 14-20 (1995).
	Lazier, C.B., et al., "Comparison of the Effects of Tamoxifen and of a Tamoxifen Analogue that Does Not Bind the Estrogen Receptor on Serum Lipid Profiles in the Cockerel", <u>Biochem. Cell Biol.</u> , <u>68</u> , 210-217 (1990).

Examiner

Date Considered

*Substitute Disclosure Statement Form (PTO-1449)

**EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449*	Atty. Docket No.: 295.009US4	Serial No. Unknown
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Applicant: David J. Grainger et al.	
	Filing Date: Herewith	Group: Unknown

OTHER DOCUMENTS

(Including Author, Title, Date, Pertinent Pages, Etc.)

**Examiner
Initial

	Lefer, "Role of Transforming Growth Factor Beta is Cardioprotection of the Ischemic-Reperfused Myocardium", <u>Growth Factors and the Cardiovascular System</u> , P. Cummins, ed., Kluwer Academic Publishers, 249-260 (1993).
	Lefer, et al., "Mechanisms of the Cardioprotective Effect of Transforming Growth Factor B1 in Feline Myocardial Ischemia and Reperfusion", <u>PNAS (USA)</u> , <u>90</u> , 1018-1022 (1993).
	Lefer, A.M., et al., "Mediation of Cardioprotection by Transforming Growth Factor Beta", <u>Science</u> , <u>249</u> , 61-64 (1990).
	Lehmann, K., et al., "Effect of cilazapril on the proliferative response after vascular damage", <u>J. of Cardiovascular Pharmacology</u> , <u>22</u> , S19-24 (1993).
	Lehmann-Bruinsma, et al., "Transforming Growth Factor B2 (TGF-B) Suppression of Smooth Muscle Cell (SMC) Proliferation After Balloon Angioplasty of Rat Carotid Arteries", <u>Clin. Res.</u> , <u>42</u> , Abstract No. 4A (1994).
	Leroux, et al., "New Approach for the Preparation of Nanoparticles by an Emulsification-Diffusion Method", <u>Eur. J. Pharm. Biopharm</u> , <u>41</u> , 14-18 (1995).
	Leroux, J.C., et al., "Interanalization of poly(D L-lactic acid) nanoparticles by isolated human leukocytes and analysis of plasma proteins adsorbed onto the particles", <u>J. Biomed. Mater. Res.</u> , <u>28</u> , 471-481 (1994).
	Levy, M.Y., "Drug Release from Submicronized O/W Emulsion: A New In Vitro Kinetic Evaluation Model", <u>Intl. J. Pharmaceut</u> , <u>66</u> , 29-37 (1990).
	Levy, R.J., et al., "Strategies for Treating Arterial Restenosis using Polymeric Controlled Release Implants", <u>Chemical Abstracts</u> , <u>121</u> , Abstract No. 263625g, 580 (1994).
	Levy, R.J., et al., "Strategies for Treating Arterial Restonosis Using Polymeric Controlled Release Implants", <u>In: Biotechnology and Bioactive Polymers</u> , Proceedings of an American Chemical Society Symposium, Gebelein, C.G., (ed.), Plenum Press, New York, 259-268 (1994).
	Li, et al., "Structure and Dynamics of Microemulsions which Mimic the Lipid Phase of Low-Density Lipoproteins", <u>Biochimica et Biophysica Acta</u> , <u>1042</u> , 42-50 (1990).
	Liaw, et al., "Osteopontin Promotes Vascular Cell Adhesion and Spreading and is Chemotactic for Smooth Muscle Cells in Vitro", <u>Cir. Res.</u> , <u>74</u> , 214-224 (1992).

Examiner

Date Considered

*Substitute Disclosure Statement Form (PTO-1449)

**EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449*	Atty. Docket No.: 295.009US4	Serial No. Unknown
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Applicant: David J. Grainger et al.	
	Filing Date: Herewith	Group: Unknown

OTHER DOCUMENTS

(Including Author, Title, Date, Pertinent Pages, Etc.)

**Examiner
Initial

	Lin, et al., "Expression Cloning of the TGF-B Type II Receptor, a Functional Transmembrane Serine/Threonine Kinase.", <u>Cell</u> , <u>68</u> , 775-785 (1992).
	Lincoff, A.M., et al., "Local Drug Delivery for the Prevention of Restenosis", <u>Circulation</u> , <u>90</u> , 2070-2084 (1994).
	Linn, et al., "Microemulsion for Intradermal Delivery of Cetyl Alcohol and Octyl Dimethyl Paba", <u>Drug Development and Industrial Pharmacy</u> , <u>16</u> , 899-920 (1990).
	Liu, M.D., et al., "Restenosis After Coronary Angioplasty - Potential Biologic Determinants and Role of Intimal Hyperplasia", <u>Circulation</u> , <u>79</u> , 1374-87 (1989).
	Lopez-Casillas, et al., "Beta-glycan Presents Ligand to the TGF-beta Signaling Receptor", <u>Cell</u> , <u>73</u> , 1435-1444 (1993).
	Love, et al., "Effects of Tamoxifen on Cardiovascular Risk Factors in Postmenopausal Women.", <u>Annals of Internal Medicine</u> , <u>115</u> , 860-864 (1991).
	Love, et al., "Effects of Tamoxifen Therapy on Lipid and Lipoprotein Levels in Postmenopausal Patients with Node-Negative Breast Cancer", <u>J. Natl. Cancer Ins.</u> , <u>82</u> , 1327-1332 (1990).
	Luo, H., et al., "Chronic Vessel Constriction is an Important Mechanism of Restenosis After Balloon Angioplasty: An Intravascular Ultrasound Analysis", <u>Circulation</u> , <u>90</u> , 67 Scientific Sessions, Abstract No. 0318, I-61 (1994).
	Macander, et al., "Balloon Angioplasty for Treatment of In-Stent Restenosis: Feasibility, Safety, and Efficacy", <u>Catheterization and Cardiovascular Diagnosis</u> , <u>37</u> , 125-131 (1990).
	Magarian, "The Medicinal Chemistry of Nonsteroidal Antiestrogens: A Review", <u>Current Medicinal Chemistry</u> , <u>1</u> , 61-104 (1994).
	Majack, R.A., et al., "Role of PDGF-A Expression in the Control of Vascular Smooth Muscle Cell Growth by Transforming Growth Factor-B", <u>The Journal of Cell Biology</u> , <u>111</u> , 239-247 (1990).
	Majesky, M.W., et al., "Production of Transforming Growth Factor beta1 During Repair of Arterial Injury", <u>J. Clin. Invest.</u> , <u>88</u> , 904-910 (1991).
	Malcolmson, et al., "A Comparison Between Nonionic Micelles and Microemulsions as a Means of Incorporating the Poorly Water Soluble Drug Diazepam", <u>J. Pharm. Pharmacol</u> , <u>42</u> , 6P (1990).

Examiner

Date Considered

*Substitute Disclosure Statement Form (PTO-1449)

**EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449*	Atty. Docket No.: 295.009US4	Serial No. Unknown
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Applicant: David J. Grainger et al.	
	Filing Date: Herewith	Group: Unknown

OTHER DOCUMENTS

(Including Author, Title, Date, Pertinent Pages, Etc.)

**Examiner
Initial

	Marx, "CMV-p.53 Interaction May Help Explain Clogged Arteries", <u>Science</u> , <u>265</u> , 320 (1994).
	Marzocchi, A., et al., "Restenosis After Coronary Angioplasty: Its Pathogenesis and Prevention", <u>Cardiologia</u> , <u>36</u> , Translation, 309-320 (1991).
	Massague, "The transforming growth factor-B family", <u>Ann. Rev. Cell Biol.</u> , <u>6</u> , 597-641 (1990).
	McCaffrey, T.A., et al., "Fucoidan is a Non-Anticoagulant Inhibitor of Intimal Hyperplasia", <u>Biochemical and Biophysical Research Communications</u> , <u>184</u> , 773-781 (1992).
	McCaffrey, T.A., et al., "Transforming Growth Factor-beta Activity is Potentiated by Heparin via Dissociation of the Transforming Growth Factor-beta/alpha2-Macroglobulin Inactive Complex", <u>The Journal of Cell Biology</u> , <u>109</u> , 441-448 (1989).
	Mccague, et al., "An Efficient, Large Scale Synthesis of Idoxifene ((E)-1(4-(2-(N-pyrrolidino)ethoxy)-1-(4-iodophenyl)-2-phenyl-1-butene)", <u>Organic Preparations and Proc. Int.</u> , <u>26</u> , 343-346 (1994).
	Mccague, et al., "Synthesis of 4-Stannylated Tamoxifen Analogues: Useful Precursors to Radiolabelled Idoxifene and Axiridiny 4-Iodotamoxifen.", <u>J. Labelled Compounds and Pharmaceuticals</u> , <u>34</u> , 297-302 (1994).
	McCaroll, et al., "Preliminary Studies on the Regulation of Secretion of Latent Transforming Growth Factor-B (TGF-B) by Endothelial Cells in Culture.", <u>Clin. Chem.</u> , <u>36</u> , Abstract No. 0934, 1152 (1990).
	McClean, et al., "cDNA sequence of human apolipoprotein (a) is homologous to plasminogen", <u>Nature</u> , <u>330</u> 132-137 (1987).
	McCormick, et al., "Retinoid-Tamoxifen Interaction in Mammary Cancer Chemoprevention", <u>Carcinogenesis</u> , <u>7</u> , 193-196 (1986).
	McDonald, et al., "Fatal Myocardial Infarction in the Scottish Adjuvant Tamoxifen Trial.", <u>B. Med. J.</u> , <u>303</u> , 435-437 (1991).
	McQuiggan, J.D., "Tissue Distribution of Cytochalasin B After Intraperitoneal Bolus and Microencapsulated Injection in Mice and its Effect on beta-N-Acetylglucosaminidase Activity in Cultured B16-BL6 Melanoma Cells", Masters' Thesis, Syracuse University, New York, 41 p., (1988).
	Merrilees, et al., "Synthesis of TGF-B1 by Vascular Endothelial Cells is Correlated with Cell Spreading.", <u>J. Vasc. Res.</u> , <u>29</u> , 376-384 (1992).

Examiner

Date Considered

*Substitute Disclosure Statement Form (PTO-1449)

**EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449*	Atty. Docket No.: 295.009US4	Serial No. Unknown
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Applicant: David J. Grainger et al.	
	Filing Date: Herewith	Group: Unknown

OTHER DOCUMENTS**Examiner
Initial

(Including Author, Title, Date, Pertinent Pages, Etc.)

	Metcalfe, J.C., et al., "Protein Markers of Lesion Development in the Vessels of Transgenic Apo(a) Mice", <u>Journal of Cellular Biochemistry</u> , Supplement 18A, Abstract No. E212, 280 (1994).
	Metcalfe, J.C., et al., "Transforming Growth Factor-beta and the Protection From Cardiovascular Injury Hypothesis", <u>Biochemical Society Transactions</u> , 23, 403-406 (1995).
	Mintz, G.S., et al., "Chronic Compensatory Arterial Dilation Following Coronary Angioplasty: An Intravascular Ultrasound Study", <u>JACC</u> , Abstract No. 875-97, 138A (1994).
	Mintz, G.S., et al., "Geometric Remodeling is the Predominant Mechanism of Clinical Restenosis After Coronary Angioplasty", <u>JACC</u> , Abstract No. 875-42, 138A (1994).
	Mintz, G.S., et al., "Mechanisms of Late Arterial Response to Transcatheter Therapy: A Serial Quantitative Angiographic and Intravascular Ultrasound Study", <u>Circulation</u> , 90, Abstract No. 117, I-24 (1994).
	More, R.S., et al., "A Targeted Antithrombotic Conjugate with Antiplatelet and Fibrinolytic Properties which Reduces in vivo Thrombus Formation", <u>Cardiovascular Research</u> , 27, 2200-2204 (1993).
	Morisaki, et al., "Effects of transforming growth factor-B, on growth of aortic smooth muscle cells", <u>Atherosclerosis</u> , 88, 227-234 (1991).
	Mosedale, D.E., et al., "Transforming Growth Factor-beta is Correlated with Smooth Muscle Cell Differentiation in Vivo", <u>Circulation</u> , 90, 67th Scientific Session, Abstract No. 1590, I-296 (1994).
	Nabel, E.G., et al., "Direct Transfer of Transforming Growth Factor Beta 1 Group Into Arteries Stimulates Fibrocellular Hyperplasia", <u>Proc. Natl. Acad. Sci. USA</u> , 90, 10759-10763 (1993).
	Nakagawa, et al., "A Case of Acute Myocardial Infarction Intracoronary Arteries Due To Hormone Therapy.", <u>Angiology</u> , 45, 333-338 (1994).
	Navarro, S.E., et al., "Notes from Transcatheter Cardiovascular Therapeutics 1995 Conference", <u>USB Securities, Equity Research -- Medical Technology</u> , 10 p. (1995).
	Nikol, S., et al., "Expression of Transforming Growth Factor Beta 1 is Increased in Human Vascular Restenosis Lesions", <u>J. Clin. Invest.</u> , 90, 1582-1592 (1992).

Examiner

Date Considered

*Substitute Disclosure Statement Form (PTO-1449)

**EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449*	Atty. Docket No.: 295.009US4	Serial No. Unknown
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Applicant: David J. Grainger et al.	
	Filing Date: Herewith	Group: Unknown

OTHER DOCUMENTS

(Including Author, Title, Date, Pertinent Pages, Etc.)

**Examiner
Initial

	Nunes, G.L., et al., "Vitamins C and E Improve the Response to Coronary Balloon Injury in the Pig: Effect of Vascular Remodeling", <u>Circulation</u> , 88 , Abstract No. 1994, I-372 (1993).
	O'Brien, et al., "Osteopontin mRNA and Protein are Overexposed in Human Coronary Atherectomy Specimens: Clues to Lesion Calcification.", <u>Circulation</u> , 88 , Abstract No. 3330, I-609 (1993).
	O'Connor-McCourt, et al., "Latent Transforming Growth Factor-B in Serum: A Specific Complex with α 2-macroglobin", <u>J. Biol. Chem.</u> , 262 , 14090-14099 (1987).
	Ohno, et al., "Gene Therapy for Vascular Smooth Muscle Proliferation After Arterial Injury", <u>Science</u> , 265 , 781-784 (1994).
	Osborne, et al., "Microemulsions as Topical Drug Delivery Vehicles: In Vitro Transdermal Studies of a Model Hydrophilic Drug", <u>J. Pharm. Pharmacol.</u> , 43 , 451-454 (1991).
	Osipow, "Transparent Emulsion", <u>J. Soc. Cosmetic Chemists</u> , 277-285 (1963).
	Owens, G.K., et al., "Transforming Growth Factor-B-induced Growth Inhibition and Cellular Hypertrophy in Cultured Vascular Smooth Muscle Cells", <u>The Journal of Cell Biology</u> , 107 , 771-780 (1988).
	Ozer, et al., "New Roles of low density lipoproteins and vitamin E in the pathogenesis of atherosclerosis", <u>Biochem Mol. Biol. Intern</u> , 35 , 117-124 (1995).
	Palmaz, J.C., et al., "Intravascular Stents", <u>In: Advances in Vascular Surgery, Vol. 1</u> , Mosby-Year Book Inc., 107-135 (1993).
	Parthasathathy, S., et al., "A Role for Endothelial Cell Lipooxygenase in the Oxidative Modification of Low Density Lipoprotein", <u>Proc. Nat'l Acad. Sci., USA</u> , 86 , 1046-1050 (1989).
	Pathak, et al., "Enhanced Stability of Physostigmine Salicylate in Submicron o/w Emulsion", <u>International Journal of Pharmaceutics</u> , 65 , 169-175 (1990).
	Perez, J.R., et al., "Regulation of Adhesion and Growth of Fibrosarcoma Cells by NF-kb RelA Involves Transforming Growth Factor Beta", <u>Molecular and Cellular Biology</u> , 14 , 5326-5332 (1994).
	Podzimek, et al., "O/W Microemulsions", <u>J. Dispersion Science and Technology</u> , I , 341-359 (1980).

Examiner

Date Considered

*Substitute Disclosure Statement Form (PTO-1449)

**EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449*	Atty. Docket No.: 295.009US4	Serial No. Unknown
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Applicant: David J. Grainger et al.	
	Filing Date: Herewith	Group: Unknown

OTHER DOCUMENTS

(Including Author, Title, Date, Pertinent Pages, Etc.)

**Examiner
Initial

	Popma, J.J., et al., "Factors Influencing Restenosis after Coronary Angioplasty", <u>The American Journal of Medicine</u> , <u>88</u> , 1-16N--1-24N (1990).
	Post, M.J., et al., "Restenosis is Partly Due to Intimal Hyperplasia and Partly to Remodeling of the Injured Arterial Wall", <u>European Heart Journal</u> , Abstract No. P1164, 201 (1993).
	Post, M.J., et al., "The Relative Importance of Arterial Remodeling Compared with Intimal Hyperplasia in Lumen Renarrowing After Balloon Angioplasty", <u>Circulation</u> , <u>89</u> , 2816-2821 (1994).
	Post, M.J., et al., "Which Part of the Angiographic Diameter Reduction After Balloon Dilation is Due to Intimal Hyperplasia?", <u>JACC</u> , <u>21</u> , Abstract No. 851-95, I-36A (1993).
	Potter, et al., "A Mechanism Hypothesis for DNA Adduct Formation Following Hepatic Oxidative Metabolism.", <u>Carcinogenesis</u> , <u>15</u> , 439-442 (1994).
	Pouton, C.W., "Self-Emulsifying Drug Delivery Systems: Assessment of the Efficiency of Emulsification", <u>International Journal of Pharmaceutics</u> , <u>27</u> , 335-348 (1985).
	Raloff, "Tamoxifen Puts Cancer on Starvation Diet", <u>Science News</u> , <u>146</u> , 292 (1994).
	Rauterberg, J., et al., "Collagens in Atherosclerotic Vessel Wall Lesions", <u>Current Topics in Pathology</u> , <u>87</u> , 163-192 (1993).
	Reid, V.C., et al., "Fragmentation of DNA in P388D, Macrophages Exposed to Oxidized Low-Density Lipoprotein", <u>FEBS Letters</u> , <u>332</u> , 218-220 (1993).
	Reiner, Z., et al., "Antiestrogen Tamoxifen Reduces Lipoprotein(a)", Abstracts, The Second International Conference on Lipoprotein (a), New Orleans, LA, 124 (1992).
	Riessen, R., et al., "Prospects for Site-Specific Delivery of Pharmacologic and Molecular Therapies", <u>Journal of the American College of Cardiology</u> , <u>23</u> , 1234-1244 (1994).
	Ross, R., "The Pathogenesis of Atherosclerosis: A Perspective for the 1990s", <u>Nature</u> , <u>362</u> , 801-809 (1993).
	Ross, R., et al., "Chronic Inflammation, PGF, TGFbeta, and Smooth Muscle Proliferation", <u>J. Cell. Biochem.</u> , <u>S15C</u> , Abstract No. H006, 142 (1991).

Examiner

Date Considered

*Substitute Disclosure Statement Form (PTO-1449)

**EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449*	Atty. Docket No.: 295.009US4	Serial No. Unknown
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Applicant: David J. Grainger et al.	
	Filing Date: Herewith	Group: Unknown

OTHER DOCUMENTS**Examiner
Initial

(Including Author, Title, Date, Pertinent Pages, Etc.)

	Ross, R., et al., "Chronic Inflammation, PDGF, TFTB, and Smooth Muscle Proliferation", <u>Molecular Mechanisms of Vascular Diseases</u> , Abstract No. G006, 96 (1991).
	Rutsch, W., et al., "Benestent-II Pilot Study: 6 Months Follow Up of Phase 1", <u>Abstract, Society of Cardiology</u> , (1995).
	Sagitani, et al., "Microemulsion Systems with a Nonionic Cosurfant", <u>J. Dispersion Science and Technology</u> , <u>1</u> (2), 151-164 (1980).
	Sanders, et al., "Controlled Release of a Lutenizing Hormone-Releasing Hormone Analogue from Poly(d,l-lactide-co-glycolide) Microspheres.", <u>J. Pharmaceutical Science</u> , <u>73</u> , 1294-1297 (1984).
	Sanderson, J.A., et al., "Antibody-Coated Microspheres for Drug Delivery to Prevent Restenosis", <u>Circulation</u> , <u>90</u> , Abstract No. 2734, I-508 (1994).
	Schatz, R.A., et al., "A View of Vascular Stents", <u>Circulation</u> , <u>79</u> , 445-457 (1989).
	Schneiderman, et al., "Increased Type 1 Plasminogen Activator Inhibitor Gene Expression in Atherosclerotic Human Arteries.", <u>PNAS (USA)</u> , <u>89</u> , 6998-7002 (1992).
	Schoenemanne, et al., "The Differential Diagnoses of Spontaneous Pneumothorax and Pulmonary Lymphangioleiomyomatosis Clinical Picture Diagnoses and Theory.", <u>Chirag</u> , <u>61</u> , 301-303 (1990); reported in <u>Biosis</u> , <u>90</u> , 432367 (1990). English abstract only.
	Schwartz, R.S., et al., "Restenosis After Balloon Angioplasty -- A Practical Proliferative Model in Porcine Coronary Arteries", <u>Circulation</u> , <u>82</u> , 2190-2200 (1990).
	Schwartz, R.S., et al., "The Restenosis Paradigm Revisted: An Alternative Proposal for Cellular Mechanisms", <u>JACC</u> , <u>20</u> , 1284-1293 (1992).
	Sedlacek, S., "Estrogenic Properties of Tamoxifen on Serum Lipids in Postmenopausal Women with Breast Cancer (BCA)", <u>Breast Cancer Research and Treatment</u> , <u>14</u> , Abstract No. 82, 153 (1989).
	Serruys, P.W., et al., "A Comparison of Balloon-Expandable-Stent Implantation with Balloon Angioplasty in Patients with Coronary Artery Disease", <u>The New England Journal of Medicine</u> , <u>331</u> , 489-495 (1994).

Examiner

Date Considered

*Substitute Disclosure Statement Form (PTO-1449)

**EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449*	Atty. Docket No.: 295.009US4	Serial No. Unknown
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Applicant: David J. Grainger et al.	
	Filing Date: Herewith	Group: Unknown

OTHER DOCUMENTS

(Including Author, Title, Date, Pertinent Pages, Etc.)

**Examiner
Initial

	Serruys, P.W., et al., "Heparin-Coated Palmaz-Schatz Stents in Human Coronary Arteries -- Early Outcome of the Benestent-II Pilot Study", <u>Circulation</u> , <u>93</u> , 412-422 (1996).
	Shanahan, C.M., et al., "High Expression of Genes for Calcification-regulating Proteins in Human Atherosclerotic Plaques", <u>Journal of Clinical Investigation</u> , <u>93</u> , 2393-2402 (1994).
	Shanahan, C.M., et al., "Isolation of Gene Markers of Differentiated and Proliferating Vascular Smooth Muscle Cells", <u>Circulation Research</u> , <u>73</u> , 193-204 (1993).
	Shewmon, et al., "Tamoxifen and Estrogen Lower Circulating Lipoprotein(a) Concentrations in Healthy Postmenopausal Women", <u>Arteriosclerosis and Thrombosis</u> , <u>14</u> , 1589-1593 (1994).
	Shewmon, et al., "Tamoxifen Decreases Lipoprotein (a) in Patients with Breast Cancer.", <u>Metabolism</u> , <u>43</u> , 531-532 (1994).
	Shewmon, D.A., et al., "Tamoxifen Lowers Lp(a) in Males with Heart Disease", <u>Supplement I Circulation</u> , <u>86</u> , 1345 (1992).
	Shoji, et al., "Enhancement of Anti-Inflammatory Effects of Biphenyllylactic Acid by its Incorporation into Lipid Microspheres.", <u>J. Pharm. Pharmacol</u> , <u>38</u> , 118-121 (1986).
	Siebenlist, U., et al., "Structure, Regulation and Function of NF-kB", <u>Annu. Rev. Cell. Biol.</u> , <u>10</u> , 405-455 (1994).
	Singh, et al., "Phylogenetic Analysis of Platelet-derived Growth Factor by Radio-Receptor Assay.", <u>J. Cell Biol.</u> , <u>95</u> , 667-671 (1982).
	Sismondi, et al., "Metabolic Effects of Tamoxifen in Postmenopause.", <u>Anticancer Res.</u> , <u>14</u> , 2237-2244 (1994).
	Snow, A.D., et al., "Heparin Modulates the Composition of the Extracellular Matrix Domain Surrounding Arterial Smooth Muscle Cells", <u>American Journal of Pathology</u> , <u>137</u> , 313-330 (1990).
	Song, C., "Dexamethasine-nanoparticles for intra-arterial localization in restenosis in rats", <u>Proceec. Intern. Symp. Control. Rel. Mater</u> , <u>22</u> , 444-445 (1995).
	Speir, et al., "Potential Role of Human Cytomegalovirus and p53 Interaction in Coronary Restenosis", <u>Science</u> , <u>265</u> , 391-394 (1994).

Examiner

Date Considered

*Substitute Disclosure Statement Form (PTO-1449)

**EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449*	Atty. Docket No.: 295.009US4	Serial No. Unknown
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Applicant: David J. Grainger et al.	
	Filing Date: Herewith	Group: Unknown

OTHER DOCUMENTS

(Including Author, Title, Date, Pertinent Pages, Etc.)

**Examiner
Initial

	Steele, P.M., et al., "Balloon Angioplasty -- Nature History of the Pathophysiological Response to Injury in a Pig Model", <u>Circulation Research</u> , <u>57</u> , 105-112 (1985).
	Stouffer, et al., "TGF beta Has a Biphasic, Concentration Dependent Effect on EFG and PDGR-BB Induced Smooth Muscle Cell Proliferation, Inflammation, Growth Regulatory Molecules and Atherosclerosis.", <u>J. Cellular Biochem, Supplement 18A</u> , Abstract No. A321, 288 (1994).
	Streuli, C.H., et al., "Extracellular Matrix Regulates Expression of the TGF-Beta 1 Gene", <u>J. Cell Biol.</u> , <u>120</u> , 253-260 (1993).
	Suckling, K.E., "Atherosclerosis Patents: Clues to the Next Drug Generation", <u>Bio/Technology</u> , <u>12</u> , 1379-1380 (1994).
	Suckling, K.E., "Emerging Strategies for the Treatment of Atherosclerosis as Seen from the Patent Literature", <u>Biochemical Society Transactions</u> , <u>21</u> , 660-662 (1993).
	Tanaka, et al., "Prominent Inhibitory Effects of Tranilast on Migration and Proliferation of and Collagen Synthesis by Vascular Smooth Muscle Cells.", <u>Atherosclerosis</u> , <u>107</u> , 179-185 (1994).
	Tice, et al., "Biodegradable controlled-release parental systems", <u>Pharmaceutical Technology</u> , 26-35 (1984).
	Topol, E.J., et al., "The Restenosis "Antitheory"", <u>Mayo Clin. Proc.</u> , <u>68</u> , 88-90 (1993).
	Vanhoutte, "Hypercholesterolaemia, Atherosclerosis and Release of Endothelium-Derived Relaxing Factor by Aggregating Platelets", <u>Eur. Heart J.</u> , <u>12, Suppl. E</u> , 25-32 (1991).
	Vargas, et al., "Oestradiol Inhibits Smooth Muscle Cell Proliferation of Pig Coronary Artery.", <u>Br. J. Pharmacol.</u> , <u>109</u> , 612-617 (1993).
	Wakefield, et al., "Latent Transforming Growth Factor-B from Human Platelets: A High Molecular Weight Complex Containing Precursor Sequences.", <u>J. Biol. Chem.</u> , <u>263</u> , 7646-7654 (1988).
	Wakefield, et al., "Recombinant Latent Transforming Growth Factor-B, has a Longer Plasma Half-Life in Rats than Active Transforming Growth Factor-B, and a Different Tissue Distribution.", <u>J. Clin. Invest.</u> , <u>86</u> , 1976-1984 (1990).

Examiner

Date Considered

*Substitute Disclosure Statement Form (PTO-1449)

**EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449*	Atty. Docket No.: 295.009US4	Serial No. Unknown
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Applicant: David J. Grainger et al.	
	Filing Date: Herewith	Group: Unknown

OTHER DOCUMENTS

(Including Author, Title, Date, Pertinent Pages, Etc.)

****Examiner**
Initial

	Waksman, R., et al., "Intracoronary Radiation Before Stent Implantation Inhibits Neointima Formation in Stented Porcine Coronary Arteries", <u>Circulation</u> , <u>92</u> , 1383-1386 (1995).
	Watson, et al., "TGF-B1 and 25-Hydroxcholesterol Stimulate Osteoblast-Like Vascular Cells to Calcify", <u>J. Clin. Invest.</u> , <u>93</u> , 2106-2113 (1994).
	Weissberg, P.L., et al., "Approaches to the Development of Selective Inhibitors of Vascular Smooth Muscle Cell Proliferation", <u>Cardiovascular Research</u> , <u>27</u> , 1191-1198 (1993).
	Weissberg, P.L., et al., "Effects of TGF-Beta on Vascular Smooth Muscle Cell Growth", <u>In: Growth Factors and the Cardiovascular System</u> , Cummins, P., (ed.), Kluwer Academic Publishers, 189-205 (1993).
	Weissberg, P.L., et al., "Is Vascular Smooth Muscle Cell Proliferation Beneficial?", <u>Lancet</u> , <u>347</u> , 305-307 (1996).
	Weissberg, P.L., et al., "The Endothelin Peptides ET-1, ET-2, ET-3 and Sarafotoxin S6b are Co-mitogenic with Platelet-Derived Growth Factor for Vascular Smooth Muscle Cells", <u>Atherosclerosis</u> , <u>85</u> , 257-262 (1990).
	Wight, T.N., "The Extracellular Matrix and Atherosclerosis", <u>Current Opinion in Lipidology</u> , <u>6</u> , 326-334 (1995).
	Wilensky, R.L., et al., "Direct Intraarterial Wall Injection of Microparticles via a Catheter: A Potential Drug Delivery Strategy Following Angioplasty", <u>American Heart Journal</u> , <u>122</u> , 1136-1140 (1991).
	Winslow, R., "Going for the Flow", <u>The Wall Street Journal</u> , (1995).
	Wiseman, H., "Tamoxifen as an Antioxidant and Cardioprotectant", <u>Biochem. Soc. Symp.</u> , <u>61</u> , 209-219 (1995).
	Wolf, Y.G., et al., "Antibodies Against Transforming Growth Factor Beta1 Suppress Intimal Hyperplasia in a Rat Model", <u>J. Clin. Invest.</u> , <u>93</u> , 1172-1178 (1994).
	Wolinsky, H., et al., "Use of a Perforated Balloon Catheter to Deliver Concentrated Heparin Into the Wall of the Normal Canine Artery.", <u>JACC</u> , <u>15</u> , 475-481 (1990).
	Wrana, et al., "Mechanism of Activation of the TGF-B Receptor", <u>Nature</u> , <u>370</u> , 341-347 (1994).

Examiner

Date Considered

*Substitute Disclosure Statement Form (PTO-1449)

**EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449*	Atty. Docket No.: 295.009US4	Serial No. Unknown
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Applicant: David J. Grainger et al.	
	Filing Date: Herewith	Group: Unknown

OTHER DOCUMENTS

(Including Author, Title, Date, Pertinent Pages, Etc.)

****Examiner
Initial**

	Yang, N.N., et al., "Estrogen Receptor: One Transcription Factor, Two Genomic Pathways", <u>Calcified Tissue Intl.</u> , <u>54</u> , 342 (1994).
	Young, H., et al., "Pharmacokinetics and Biodistribution of Radiolabelled Idoxifene: Prospects for the Use of PET in the Evaluation of a Novel Antioestrogen for Cancer Therapy", <u>Nucl. Med. Biol.</u> , <u>22</u> , 405-411 (1995).
	Zuckerman, et al., "Cytokine Regulation of Macrophage apo E. Secretion: Opposing Effects of GM-CSF and TGF-B.", <u>Atherosclerosis</u> , <u>96</u> , 203-214 (1992).
	Zuckerman, et al., "Exogenous Glucocorticoids Increase Macrophage Secretion of apo E by Cholesterol Independent Pathways.", <u>Atherosclerosis</u> , <u>103</u> , 43-54 (1993).

Examiner

Date Considered

*Substitute Disclosure Statement Form (PTO-1449)

**EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449*	Atty. Docket No.: 295.009US4	Serial No. Unknown
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Applicant: David J. Grainger et al.	
	Filing Date: Herewith	Group: Unknown

US PATENT DOCUMENTS						
Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	Filing Date If Appropriate
	5,411,988	05/02/1995	Bockow et al.	514	560	10/27/1993
	5,445,941	08/29/1995	Yang	435	6	06/21/1993
	5,446,070	08/29/1995	Mantelle	514	772.6	08/27/1993
	5,496,851	03/05/1996	Grinnell	514	443	04/14/1995
	5,605,700	02/25/1997	DeGregorio et al.	424	448	10/31/1994
	5,652,259	07/29/1997	May	514	422	05/09/1996
	6,410,587	06/25/2002	Grainger et al.	514	445	05/05/2000

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Foreign Document No	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	T ²
	EP 0 377 526	07/11/1990	Abdel-Monem et al.	C07F	1/08	
	EP 0 675 103	10/04/1995	Horrobin et al.	C07C	69/612	
	EP 0 684 259	11/29/1995	Koyama et al.	C07K	5/09	
	WO 96/21442	07/18/1996	Korsaard et al.	A61K	31/40	

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		"Schering/Orion <i>Fareston</i> Anti-Estrogen for Treatment of Metastatic Breast Cancer 'Similar' to Tamoxifen, FDA Oncologic Committee Says in Approval Vote", <i>F-D-C Reports</i> , 15-16 (1995).	
		HARDCASTLE et al., "Homologs of Idoxifene: Variation of Estrogen Receptor Binding and Calmodulin Antagonism with Chain Length", <i>J. Med. Chem.</i> , 39 , 999-1004 (1996).	
		HAYES et al., "Randomized Comparison of Tamoxifen and Two Separate Doses of Toremifene in Postmenopausal Patients with Metastatic Breast Cancer", <i>Journal of Clinical Oncology</i> , 13 , 2556-2566 (1995).	
		JONES et al., "Increased Susceptibility to Metal Catalysed Oxidation of Diabetic Lens β_L Crystallin: Possible Protection by Dietary Supplementation with Acetylsalicylic Acid", <i>Exp. Eye Res.</i> , 57 , 783-790 (1993).	
		LOSER et al., " <i>In Vivo</i> and <i>in Vitro</i> Antiestrogenic Action of 3-Hydroxytamoxifen, Tamoxifen and 4-Hydroxytamoxifen", <i>Eur. J. Cancer Clin. Oncol.</i> , 21 , 985-990 (1985).	

Examiner

Date Considered

*Substitute Disclosure Statement Form (PTO-1449)

**EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449*	Atty. Docket No.: 295.009US4	Serial No. Unknown
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Applicant: David J. Grainger et al.	
	Filing Date: Herewith	Group: Unknown

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		MOORTHY et al., "Tamoxifen Metabolic Activation: Comparison of DNA Adducts Formed by Microsomal and Chemical Activation of Tamoxifen and 4-Hydroxytamoxifen with DNA Adducts Formed in Vivo", <u>Cancer Research</u> , <u>56</u> , 53-57 (1996).	
		MURPHY et al., "Differential Effects of Tamoxifen and Analogs with Nonbasic Side Chains on Cell Proliferation <i>in Vitro</i> ", <u>Endocrinology</u> , <u>116</u> , 1071-1078 (1985).	
		MURPHY et al., "Structure-Activity Relationships of Nonisomerizable Derivatives of Tamoxifen: Importance of Hydroxyl Group and Side Chain Positioning for Biological Activity", <u>Molecular Pharmacology</u> , <u>39</u> , 421-428 (1991).	
		SARGENT et al., "Induction of Hepatic Aneuploidy <i>in Vivo</i> by Tamoxifen, Toremifene and Idoxifene in Female Sprague-Dawley Rats", <u>Carcinogenesis</u> , <u>17</u> , 1051-1056 (1996).	

Examiner	Date Considered
----------	-----------------

*Substitute Disclosure Statement Form (PTO-1449)

**EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449*

Atty. Docket No.: 295.009US4

Serial No. Unknown

INFORMATION DISCLOSURE STATEMENT
BY APPLICANT

(Use several sheets if necessary)

Applicant: David J. Grainger et al.

Filing Date: Herewith

Group: Unknown

US PATENT DOCUMENTS

Examiner Initial *	Document Number	Date	Name of Patentee or Applicant of Document	Class	Subclass	Filing Date
	4,282,246	08/04/1981	Holland	424	275	03/07/1980
	4,287,190	09/01/1981	Boettcher et al.	424	230	11/29/1979
	4,310,523	01/12/1982	Neumann	424	240	10/10/1980
	4,317,915	03/02/1982	Confalone et al.	549	68	01/14/1980
	4,382,143	05/03/1983	Shepherd	549	68	07/23/1979
	4,428,963	01/31/1984	Confalone et al.	424	275	03/10/1983
	4,440,754	04/03/1984	Sorenson	424	140	05/23/1980
	4,629,694	12/16/1986	Harpel	435	7	07/12/1983
	4,758,555	07/19/1988	Sorenson	514	186	12/08/1986
	4,767,758	08/30/1988	Breccia et al.	514	231.5	02/26/1987
	4,952,607	08/28/1990	Sorenson	514	589	01/30/1986
	4,999,347	03/12/1991	Sorenson	514	159	10/20/1989
	5,082,834	01/21/1992	Sorenson	514	159	09/18/1990
	5,118,791	06/02/1992	Burnier et al.	530	326	06/13/1991
	5,280,040	01/18/1994	Labroo et al.	514	422	03/11/1993
	5,332,576	07/26/1994	Mantelle	424	443	05/21/1993
	5,420,243	05/30/1995	Ogawa et al.	530	324	01/26/1993
	5,451,603	09/19/1995	Piggott	514	422	03/11/1993
	5,453,492	09/26/1995	Bützow et al.	530	413	07/28/1993
	5,480,903	01/02/1996	Piggott	514	422	04/17/1994
	5,482,851	01/09/1996	Derynck et al.	435	240.1	11/05/1993
	5,484,797	01/16/1996	Bryant et al.	514	319	04/21/1995
	5,521,172	05/28/1996	Bryant et al.	514	212	08/15/1995
	5,552,433	09/03/1996	Bryant et al.	514	443	08/15/1995
	5,556,876	09/17/1996	Bryant et al.	514	443	08/15/1995
	5,610,168	03/11/1997	Draper	514	333	04/14/1995
	5,641,790	06/24/1997	Draper	514	333	04/14/1995
	5,658,883	08/19/1997	Ogawa et al.	514	12	03/08/1995
	5,658,951	08/19/1997	Magarian et al.	514	596	06/07/1995
	5,686,476	11/11/1997	May	514	324	03/15/1995
	5,688,813	11/18/1997	Sall et al.	514	324	04/14/1995
	5,747,510	05/05/1998	Draper	514	333	01/27/1997
	5,773,479	06/30/1998	Grainger et al.	514	651	11/21/1995
	5,824,647	10/20/1998	Postlethwaite et al.	514	13	06/01/1995
	6,166,090	12/26/2000	Grainger et al.	514	651	11/06/1997
	6,197,789	03/06/2001	Grainger et al.	514	319	06/07/1996
	6,251,920	06/26/2001	Grainger et al.	514	319	05/21/1998
	6,262,079	07/17/2001	Grainger et al.	514	319	05/06/1999

Examiner

Date Considered

*Substitute Disclosure Statement Form (PTO-1449)

**EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449*

Atty. Docket No.: 295.009US4

Serial No. Unknown

INFORMATION DISCLOSURE STATEMENT
BY APPLICANT

(Use several sheets if necessary)

Applicant: David J. Grainger et al.

Filing Date: Herewith

Group: Unknown

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Foreign Document No	Publication Date		Class	Subclass	T ²
	EP 0 002 341	06/13/1979		C07C	65/10	
	EP 0 024 096	02/25/1981		C07F	1/08	
	EP 0 302 034	02/01/1989		C08B	37/10	
	EP 0 659 418	06/28/1995		A61K	31/445	
	JP 9255570	03/21/1996		A61K	31/35	Abstract
	JP 6025288	02/01/1994				Abstract
	JP 59042375	03/08/1984		C07D	333/32	Abstract
	GB 1,587,084	03/25/1981				
	WO 85/00107	01/17/1985		A61K	31/13	Full
	WO 94/20098	09/15/1994		A61K	31/40	
	WO 94/20099	09/15/1994		A61K	31/40	
	WO 94/26303	11/24/1994		A61K	39/00	
	WO 94/26888	11/24/1994		C12N	15/11	
	WO 94/28721	12/22/1994		A01N	43/42	
	WO 95/05191	02/23/1995		A61K	38/00	
	WO 95/17095	06/29/1995		A01N	43/38	
	WO 96/07402	03/14/1996		A61K	31/075	
	WO 96/21443	07/18/1996		A61K	31/40	
	WO 96/40098	12/19/1996		A61K	31/135	

Examiner Initials*	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	"Health Report -- The Good News", Time, 23 (1996).
	"Heparin", In: Modern Pharmacology, Craig, C.R., et al., (eds.), Little, Brown and Company, Boston, MA, 399 (1982).
	ASCHERMANN, "Restenosis after percutaneous transluminal coronary angioplasty. Pathophysiology, new trends in prevention and treatment", Cor Vasa, 36, 211-218 (1994).
	BAGDADE et al., "Effects of Tamoxifen Treatment on Plasma Lipids and Lipoprotein Lipid Composition", J. Clinical Endocrinology and Metabolism, 70, 1132-1135 (1990).
	BAQUIAL et al., "Down-Regulation of NADPH-Diaphorase (Nitric Oxide Synthase) May Account for the Pharmacological Activities of Cu(II) ₂ (3,5-Diisopropylsalicylate) ₄ ", J. Inorganic Biochem., 60, 133-148 (1995).
	CUNNINGHAM et al., "A Study of the Structural Basis of the Carcinogenicity of Tamoxifen, Toremifene and their Metabolites", Mutation Research, 349, 85-94 (1996).
	DEALVARE et al., "Mechanism of Superoxide Anion Scavenging Reaction by Bis-(Salicylato)-Copper(II) Complex", Biochemical and Biophysical Research Communications, 69, 687-694 (1976).
	DEHMER et al., "Reduction in the Rate of Early Restenosis After Coronary Angioplasty by a Diet Supplemented with n-3 Fatty Acids", N. Engl. J. Med., 319, 733-740 (1988).

Examiner

Date Considered

*Substitute Disclosure Statement Form (PTO-1449)

**EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449*	Atty. Docket No.: 295.009US4	Serial No. Unknown
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Applicant: David J. Grainger et al.	
	Filing Date: Herewith	Group: Unknown

OTHER DOCUMENTS

(Including Author, Title, Date, Pertinent Pages, Etc.)

**Examiner
Initial

Examiner Initials*	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	FRYE et al., "Oxolanosterol Oximes: Dual-Action Inhibitors of Cholesterol Biosynthesis", <u>Journal of Lipid Research</u> , 35, 1333-1344 (1994).
	GARG et al., "Nitric Oxide-Generating Vasodilators and 8-Bromo-Cyclic Guanosine Monophosphate Inhibit Mitogenesis and Proliferation of Cultured Rat Vascular Smooth Muscle Cells", <u>Journal of Clinical Investigation</u> , 83, 1774-1777 (1989).
	GOODNIGHT, "The Effects of n-3 Fatty Acids on Atherosclerosis and the Vascular Response to Injury", <u>Arch. Pathol. Lab. Med.</u> , 117, 102-106 (1993).
	GRAINGER, "Taking Tamoxifen To Heart", <u>Nature Medicine</u> , 1, 1226 (1995).
	GRAINGER et al., "Tamoxifen Elevates Transforming Growth Factor- β and Suppresses Diet-Induced Formation of Lipid Lesions in Mouse Aorta", <u>Nature Medicine</u> , 1, 1067-1073 (1995).
	GRIGG et al., "Determinants of Restenosis and Lack of Effect of Dietary Supplementation with Eicosapentaenoic Acid on the Incidence of Coronary Artery Restenosis After Angioplasty", <u>JACC</u> , 13, 665-672 (1989).
	GUETTA et al., "Effects of the Antiestrogen Tamoxifen on Low-Density Lipoprotein Concentrations and Oxidation in Postmenopausal Women", <u>The American Journal of Cardiology</u> , 76, 1072-1073 (1995).
	GYLLING et al., "Tamoxifen Decreases Serum Cholesterol by Inhibiting Cholesterol Synthesis", <u>Atherosclerosis</u> , 96, 245-247 (1992).
	KEEN et al., "Hypertension Induced Alterations in Copper and Zinc Metabolism: A Link to Vascular Disease?", In: <u>Biology of Copper Complexes</u> , Sorenson, J.R.J., (ed.), Humana Press, Clifton, New Jersey, 141-153 (1987).
	KURAMOCHI, "Conformational Studies and Electronic Structures of Tamoxifen and Toremifene and Their Allylic Carbocations Proposed as Reactive Intermediates Leading to DNA Adduct Formation", <u>J. Med. Chem.</u> , 39, 2877-2886 (1996).
	MILNER et al., "Usefulness of Fish Oil Supplements in Preventing Clinical Evidence of Restenosis After Percutaneous Transluminal Coronary Angioplasty", <u>Am. J. Cardiol.</u> , 64, 294-299 (1989).
	O'LEARY et al., "The Resistance of Low Density Lipoprotein to Oxidation Promoted by Copper and Its Use as an Index of Antioxidant Therapy", <u>Atherosclerosis</u> , 119, 169-179 (1996).
	REIS et al., "Randomised Trial of Fish Oil for Prevention of Restenosis After Coronary Angioplasty", <u>The Lancet</u> , 177-181 (1989).

Examiner

Date Considered

*Substitute Disclosure Statement Form (PTO-1449)

**EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449*	Atty. Docket No.: 295.009US4	Serial No. Unknown
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Applicant: David J. Grainger et al.	
	Filing Date: Herewith	Group: Unknown

OTHER DOCUMENTS

(Including Author, Title, Date, Pertinent Pages, Etc.)

**Examiner
Initial

Examiner Initials*	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	SAARTO et al., "Antiatherogenic Effects of Adjuvant Antiestrogens: A Randomized Trial Comparing the Effects of Tamoxifen and Toremifene on Plasma Lipid Levels in Postmenopausal Women with Node-Positive Breast Cancer", <u>Journal of Clinical Oncology</u> , 14, 429-433 (1996).
	SORENSEN, "Pharmacological Activities of Copper Compounds", In: <u>Handbook of Metal-Ligand Interactions in Biological Fluids -- Bioinorganic Medicine</u> , 2, Berton, G., (ed.), Marcel Dekker, Inc., New York, 1128-1139 (1995).
	VON SCHACKY et al., "Long-Term Effects of Dietary Marine ω -3 Fatty Acids upon Plasma and Cellular Lipids, Platelet Function, and Eicosanoid Formation in Humans", <u>J. Clin. Invest.</u> , 76, 1626-1631 (1985).
	WILLIAMS et al., "The Estrogen Receptor Agonist/Antagonist Tamoxifen Inhibits Progression of Coronary Artery Atherosclerosis in Monkeys", <u>Circulation</u> , 92, November 1995 AHA Meeting, (1995).

Examiner	Date Considered
----------	-----------------

*Substitute Disclosure Statement Form (PTO-1449)

**EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.